UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

ALFA INTERNATIONAL SEAFOOD, INC., *et al.*,

Plaintiffs

v.

WILBUR ROSS, et al.,

Defendants.

Case No. 1:17-cv-00031-APM

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Robert P. Charrow (DC 261958) Laura Metcoff Klaus (DC 294272) GREENBERG TRAURIG LLP 2101 L Street, N.W., Suite 1000 Washington, D.C. 20037 Tele: 202-533-2396; Fax: 202-261-0164 Email: charrowr@gtlaw.com; klausl@gtlaw.com

Counsel for Plaintiffs

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Plaintiffs challenge regulations issued by the United States National Marine Fisheries Service ("NMFS"), on December 9, 2016, that, in effect, require American companies to enforce foreign laws by "help[ing] authorities verify that ... [imported] fish or fish products were lawfully acquired by providing information to trace each import shipment back to the initial harvest event(s)" and to "decrease the incidence of seafood fraud." Administrative Record ("AR") 6907: 81 Fed. Reg. 88,975 (Dec. 9, 2016).¹ These are the wrong rules issued by the wrong agency and the wrong person at the wrong time. Plaintiffs request that this Court enter summary judgment in their favor and vacate these rules.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

Illegal, unreported, and unregulated ("IUU") fishing is a global concern. Various international as well as domestic organizations have recognized the need to improve international regulation of seafood to better ensure that the harvesting or catching of fish is legal and reported and that seafood sold to consumers is accurately labeled or portrayed. The United Nations Food and Agricultural Organization ("FAO") has advocated a global solution to this global problem, in accordance with international law, and has urged nations to refrain from unilateral trade-related measures when responding to the challenge of IUU fishing. A number of international regional fisheries management organizations, including some in which the United States participates, have adopted management and enforcement measures aimed at reducing IUU fishing. In the European Union ("EU") and elsewhere, the Marine Stewardship Council ("MSC") implements fishery and traceability standards. *See* AR 7526-27. The Western and Central Pacific Fisheries Convention, the International Convention for the Conservation of Atlantic Tunas, the Northwest Atlantic Fisheries Organization, and the Commission for the Conservation of Antarctic Marine Living Resources all have developed a variety of innovative catch documentation and trade

¹ NMFS is a non-independent agency within the National Oceanic and Atmospheric Administration ("NOAA") which, in turn, is a non-independent agency within the Department of Commerce ("Commerce").

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tracking requirements that enable governments to monitor the movement of fish and fish products through international commerce.

Domestically, the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006 ("MSA"), among other things, required the Secretary of Commerce to define the term "illegal, unreported, or unregulated fishing." 16 U.S.C. § 1826j(e); *see* 50 C.F.R. § 300.201 (defining term). The MSA, however, does not address seafood fraud. In June 2014, the White House established a Presidential Task Force on Combating IUU Fishing and Seafood Fraud which, in December 2014, issued various recommendations to the President, aimed at combating both IUU fishing and seafood fraud. *See* AR 1: Presidential Task Force on Combating IUU Fishing and Seafood Fraud: Action Plan for Implementing the Task Force Recommendations. Of the fifteen recommendations, two suggested the development of a traceability program based on the risk of IUU fishing and seafood fraud. Finally, in November, 2015, Congress enacted The Illegal, Unreported, and Unregulated (IUU) Fishing Enforcement Act. *See* Pub. L. No. 114-81, 129 Stat. 649 (Nov. 5, 2015), which ratified the FAO Port State Measures Agreement.²

Advances in technology also have been directed at IUU fishing. Technological advances have made it easier, less expensive and less intrusive to police IUU fishing through detailed GPS surveillance of the oceans, permitting regulators to pinpoint fishing vessels in prohibited areas. DNA testing permits importers to combat seafood fraud by confirming that the species on the label matches the species in the package. For example, Global Fishing Watch, a new, free satellite-based surveillance system powered by Google, allows governments, as well as journalists and citizens, to monitor fishing and enforce fishing restrictions world-wide. The Pew Charitable Trusts has launched a similar technology, called Project Eyes in the Sky, aimed at detecting pirate fishing. *See* Brady Dennis, How Google is Helping to Crack Down on Illegal Fishing--From Space, WASHINGTON POST (Oct. 4, 2016).

² The U.S. was the twentieth country to ratify the Port State Measures Agreement. It will take legal effect when ratified by twenty-five countries.

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It is against this background of multilateralism and advances in technology that NMFS proposed a unilateral, trade-related, supposedly risk-based seafood traceability program. That process began with the issuance on April 30, 2015, of a one-page notice by a National Ocean Council Working Group soliciting comments on the principles to be used to identify fish species likely to be most at risk of IUU fishing or seafood fraud. *See* AR 2674: 80 Fed. Reg. 24,246 (April 30, 2015). The agency received 155 comments in response to this notice.

On August 3, 2015, two months after the comment period closed, NMFS published a Notice and request for comments on a set of seven principles for identifying "at risk" species and a draft list of those species, both developed by a Working Group within NMFS. *See* AR 3970: 80 Fed. Reg. 45,955 (Aug. 3, 2015). There is no indication that any of the public comments were taken into account in fashioning the seven guiding principles.

Four of the principles appear to relate solely to IUU fishing: (i) enforcement capability, (ii) catch documentation, (iii) complexity of chain of custody and processing, and (iv) history of violation. *See* AR 3971: 80 Fed. Reg. at 45,956. The lower the enforcement capability, the poorer the catch documentation, the more complex the chain of custody and the greater the history of violation for any given species, the more likely that species would be identified as "at risk" for IUU fishing. The remaining three principles relate solely to seafood fraud: (i) history of species substitution; (ii) history of mislabeling; and (iii) human health risks as a result of substitution or mislabeling. *See id*.

Based on these seven principles, the Working Group identified thirteen at-risk species groups or seventeen species, if one distinguishes the five types of tuna: (1) Abalone; (2) Atlantic Cod; (3) Blue Crab; (4) Dolphinfish (*i.e.*, Mahi Mahi); (5) Grouper; (6) King Crab; (7) Pacific Cod; (8) Red Snapper; (9) Sea Cucumber; (10) Shark; (11) Shrimp; (12) Swordfish; and (13) Tuna (albacore, bigeye, bluefin, skipjack and yellowfin). No data were provided to support the Working Group's determinations. The Working Group also refused to take into account the country of origin even though three of the four IUU principles necessarily take country of origin into account, and it is well-known within the industry that certain nations are better at policing

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their seas and enforcing international norms than others. The Working Group instead asserted that it "does not believe it is useful or appropriate to establish a principle based on country of origin." AR 3976: 80 Fed. Reg. at 45,961 (col. a).

On October 30, 2015, Samuel D. Rauch, III, deputy assistant administrator for regulatory programs at NMFS, issued a document entitled Notice of Determination. *See* AR 4464: 80 Fed. Reg. 66,867 (Oct. 30, 2015). The issuance set out the "at risk" species identified by the Working Group with the exception of bluefin tuna, which was dropped from the list.

The Notice also responded to comments which urged that its findings should be "data driven," by stating that it "partially agrees." *Id.* at 66,872 (col. a). However, the agency did not indicate the classes of data that were used and it refused to disclose the actual data on which it relied to identify the "at risk" species, stating that "[d]etailed presentation of the data considered by the Working Group and its deliberations is protected from disclosure because of data confidentiality and enforcement implications." *Id.* at 66,870 (col. a).

With respect to comments questioning the reasonableness of treating all countries the same in terms of enforcement, *see, e.g.*, AR 4583: Comments of New Zealand, the "Working Group acknowledge[d] that the risk of IUU fishing will vary depending on the country of the origin [but] the Working Group does not believe it is useful or appropriate to establish a principle based on country of origin." AR 4469: 80 Fed. Reg. at 66,872 (col. b). The agency did not explain why it would not be useful or appropriate to take into account country of origin. AR 4469, 4473: 80 Fed. Reg. 66,872, 66,876.

Many of its other responses to significant comments were also internally inconsistent. For example, some commenters questioned the utility of using the complexity of the chain of custody as a principle for identifying IUU fishing or seafood fraud. Mr. Rauch agreed that the "Working Group does not believe that a complex chain of custody or high level of processing necessarily signifies fraudulent product or a connection to IUU fishing." AR 4470: 80 Fed. Reg. at 66,873 (col. c). But, the agency retained complexity of the chain of custody as a principle for identifying "at risk" species because in complex environments, "there are more opportunities for

mixing illegally caught fish with legally caught fish and for mislabeling." *Id.* No data were offered for this proposition or for that matter any proposition presented in the Determination. Whatever data NMFS may have had has never been publicly revealed.

B. The Proposed Rule

Three months after issuing its Determination, NMFS proposed the traceability rules that are the subject of this litigation. *See* AR 4477: 81 Fed. Reg. 6210 (Feb. 5, 2016). NMFS proposed that the rules would apply to seventeen species, adding Bluefin tuna back into the mix. It requested comment on the proposed rules, but asked "that comments not be submitted on this proposal that are duplicative of those submitted on the list of species and contain no new information." AR 4480: 81 Fed. Reg. at 6213.

The data ostensibly supporting the selection of these seventeen species still were missing from the proposed rules. When plaintiff NFI and others questioned the propriety of selecting seventeen species without revealing the data underlying the selection, NMFS reiterated that "details of the results have not been included because much of the data reviewed are sensitive and/or confidential, and could compromise the integrity of individual businesses, system or enforcement capability if released." AR 4469: 80 Fed. Reg. at 66,872 (col. a); AR 6611-66: NFI Comments at 28-31 (April 12, 2016); AR 4647: Comments of Canada's Ministry of Fisheries and Oceans at 2 (April 11, 2016) ("there remains a lack of transparency in terms of how the list of at-risk species has been developed").

NMFS proposed that U.S. seafood importers of record (or customs brokers acting on their behalf) collect and report electronically to the Government at the point of entry into U.S. commerce a long list of traceability data documenting the point of harvest up to the point of entry as a condition of importing certain wild-caught and farmed seafood into the United States for each of the seventeen species on the NMFS at-risk list, including:

- a. Name of harvesting vessel(s).
- b. Flag state of harvesting vessel(s).
- c. Evidence of authorization of harvesting vessel(s).
- d. Unique vessel identification(s) of harvesting vessel(s) (if available).

- e. Type(s) of fishing gear used in harvesting product.
- f. Names(s) of farm or aquaculture facility.
- g. Species of fish (scientific name, acceptable name, and an ASFIS [Aquatic Sciences and Fisheries Information System] number.
- h. Product description(s).
- i. Name of product(s).
- j. Quantity and/or weight of the product(s).
- k. Area(s) of wild-capture or aquaculture location.
- 1. Date(s) of harvest or trip(s).
- m. Location of aquaculture facility [Not relevant to wild caught seafood]
- n. Point(s) of first landing.
- o. Date(s) of first landing.
- p. Name of entity(ies) (processor, dealer, vessel) of first landing.
- q. NMFS-issued IFTP [International Fisheries Trade Permit] number.

AR 4483: 80 Fed. Reg. at 6216. The proposed rules also would have required the importer to possess records documenting the chain of custody between harvest and importation. Those importers that do not comply with these new traceability requirements would have their imports barred from entry into the U.S. market.

The proposed rules would make it a violation of the MSA to import any at-risk seafood without a valid IFTP or to submit inaccurate or incomplete traceability information. In addition, importers would be required to maintain records documenting the chain of custody of the product from harvest to point of importation for five years. These records would be subject to review by NOAA upon request. Import shipments of fish or fish products subject to the new traceability program could be selected for inspection, or the related records could be subjected to audit, in order to verify the information submitted at entry.

These new requirements for importers have no equivalent domestic counterpart and the new rules would not apply to domestic seafood, with the exception of U.S. wild-caught and farmed fish exported for processing and reimported into the United States. U.S. fisheries generally are not required to provide the government with this extent of data. Separate pieces of this information are required from a number of different participants along the long length of the domestic seafood supply chain, but not all of it is required of any one participant in the supply chain. The closest U.S. law comes to such a traceability program is a pilot program of the U.S.

Food and Drug Administration ("FDA") for food products that have been the subject of safety concerns in recent years. This pilot program is mandated by Section 204 of the Food Safety Modernization Act of 2010. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 also requires limited traceability for all foods. Both of these laws are administered by the Secretary of Health and Human Services.

C. Costs to Implement the Proposed Rule

The proposed rules referenced an Initial Regulatory Flexibility Act Analysis ("IRFAA") under the Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 601 *et seq.* AR 4487: 81 Fed. Reg. at 6220. An IRFAA must indicate the number of small entities subject to the regulation, a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rules, along with the professional skills necessary to prepare the documents. *See* 5 U.S.C. § 603(b). The agency is also required to publish its IRFAA in the Federal Register. *See id.* at § 603(a).

Here, the IRFAA was never published in the Federal Register. It did not indicate the number of small entities that would be affected by the rule. Nor did it describe the reporting, recordkeeping and compliance burdens or even the levels of skills necessary to comply with the rule. The IRFAA contained no assessment of costs in dollars and cents other than noting that the additional registration fees would total \$60,000 and that data entry would cost across the entire seafood sector less than \$250,000. The agency acknowledged that the rule would increase costs to those in the chain of distribution and hence to consumers but made no effort to quantify or even to assess those costs. Instead, the agency concluded, without the benefit of any data, that

[t]he permitting, electronic reporting and recordkeeping requirements proposed by this rulemaking would build on current business practices (e.g., information systems to facilitate product recalls, to maintain product quality, or to reduce risks of food borne illnesses) and are not estimated to pose significant adverse or long-term economic impacts on small entities.

AR 4487: 81 Fed. Reg. at 6220 (col. b).

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Sometime in October 2016, the Office of Management and Budget ("OMB") published through its website a table of revised costs under the Paperwork Reduction Act. The OMB table lists data entry costs across all species at \$6,475,000 for 215,000 entries. OMB estimated that there would be 215,000 import events subject to the rule and that it would take approximately 101,000 hours to enter the data or about 30 minutes for each container of seafood. Other than these data entry costs, OMB did not assess the economic impact on small businesses of the proposed rule.

More than 100 comments were filed in response to the proposed rules, many from foreign nations, *e.g.*, Australia, Canada, Norway, Peru, Thailand, India, and Malaysia, that were concerned with the agency's unilateral approach to an international issue and the agency's refusal to take country of origin into account even though there is a wealth of data that would have permitted the agency to have done so. Plaintiff NFI challenged the necessary for the rules and the cost assumptions for compliance. The Small Business Administration's Office of Advocacy ("SBA") also found that the IRFAA failed "to analyze viable alternatives," as required by the RFA and underestimated the cost of compliance. SBA commented that "[i]f a small business processed only ten containers per year, the costs would be close to \$200,000 for one business," assuming \$20,000 cost per container to enter data. AR 6496: SBA Letter at 4.

D. The Final Rule

On December 9, 2016, NMFS issued its Final Rule. AR 6907. Like the proposed rules, it was issued by Defendant Rauch, not the Secretary of Commerce. Rauch is five tiers below the Secretary on the organization chart and neither he nor his immediate supervisor (*i.e.*, Eileen Sobeck) is a presidential appointee. There is no published notice that the Secretary's rulemaking authority was delegated to any inferior officer or employee within the Department, including Rauch.

The Final Rule, for the most part, followed the basic framework set forth in the proposed rules with three exceptions. First, it temporarily suspended the Rule's applicability to two so-called "priority" species (shrimp and abalone), admitting that there was (and is) no domestic

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counterpart to the requirements it had imposed. AR 6908. However, both species remain subject to certain provisions of the Final Rule. Second, the Final Rule reduced from five years to two years the period over which importers would be required to retain records. AR 6913. Third, the Final Rule now permits a broker or processor that purchases seafood from certain small fishing boats at a single collection point on the same day to trace and transfer the data in the aggregate, rather than on a boat-by-boat basis. *Id.* Despite the agency's effort to reduce the amount of data (and thus the associated costs) necessary to be collected, maintained and transferred, it does not decrease the costs that would be incurred by processors who still need to modify the way in which their seafood is processed so that each lot of fish can be continuously traced back either to a single harvest event, in the case of larger boats, or a single collection point, in the case of smaller boats. The Department did not evaluate these costs. It gave the regulated community until January 1, 2018, to fully comply with the Final Rule. AR 6907.

E. The Lawsuit

On January 6, 2017, plaintiffs, Alfa International Seafood, Inc., Fortune Fish and Gourmet, Handy Seafood Inc., Dulcich, Inc., Pacific Seafood Processors Association, Trident Seafoods Corp., West Coast Seafood Processors Association, Libby Hill Seafood Restaurants, Inc. and National Fisheries Institute, instituted this challenge to the Final Rule. Plaintiffs alleged that (1) the rules violate the Administrative Procedure Act, 5 U.S.C. §§ 551-59, 701-706 ("APA") because they were either based on no data or on data that were not disclosed in the public record (Count 1); (2) internal inconsistencies rendered the rules arbitrary and capricious (Count 2); (3) a deputy assistant administrator for regulatory programs at NMFS (defendant Samuel D. Rauch III) lacked rulemaking authority to issue the Final Rule (Count 3); (4) the Department of Commerce lacks authority over seafood fraud (Count 4); (5) the agency's RFA analysis was legally improper (Count 5); and (6) the agency failed to conduct the cost benefit analysis required under Executive Order 12866, thus violating the MSA which incorporates that requirement (Count 6).

SUMMARY STATEMENT OF FACTS³

Plaintiffs represent all sectors of the seafood industry, from harvesters, processors, importers, distributors and retailers. Many of the plaintiffs or plaintiffs' members are small businesses within the meaning of the Small Business Act. All of the plaintiffs will be adversely affected by the Final Rule.

The Final Rule seeks to combat IUU fishing and seafood fraud by imposing elaborate reporting and recordkeeping requirements so that the government can trace each shipment of certain species of imported fish from catch to entry into the U.S. One factor used by the agency to select the seventeen species subject to the Final Rule is the complexity of the distribution chain. The more complex the greater the likelihood that the species would be subject to the rule. In the typical, complex distribution chain, seafood is harvested by small boats, sold the same day to brokers on the beach. Each broker consolidates those catches from one or more beaches, landing stations, or landing docks which it then sells to a processor. The processor, in turn, aggregates the catches from multiple brokers and prepares the fish for multiple importers simultaneously. The processor packages the product in containers which are combined in a crate. The crates are loaded into a shipping container for a single importer. Depending on the species, those containers weigh between 35,000 and 44,000 pounds and contain over 100,000 separate packages of seafood. The agency has estimated that the rule would affect 2,000 importers and 600 customs brokers making 215,000 entries per year. AR 6942: 81 Fed. Reg. 88,993 (col. c). That the Final Rule imposes increased costs on the regulated industry is undisputed.

The Final Rule will affect the way in which seafood is processed throughout the world. Even if an importer is not required to input specific data for each piece of fish in a container, the processor still must segregate seafood for processing in order to provide data to multiple

³ A complete statement of facts with record citations is set forth in plaintiffs' Local Rule 7(h)(2) Statement which is attached as Exhibit 1.

customers. The agency did not consider this significant impact. The Final Rule, based on a study relied on by the agency, will increase costs by at least ten percent.

SUMMARY OF ARGUMENT

This is an ironic rule. It is a complex rule issued by a science agency without the benefit of science or data. The Final Rule suffers from a series of fatal flaws. First, it was issued by a sixth tier bureaucrat who was not an officer and therefore lacked constitutional authority to promulgate a regulation, even assuming that such authority could be delegated to him. Here, there is no proof in the administrative record or elsewhere that such authority was delegated by the Secretary of Commerce. Second, the rule seeks to combat seafood fraud, but the agency lacks rulemaking authority in that area. Third, even if authorized and properly delegated, the rule is arbitrary and capricious because the agency has refused to publicly reveal the data that ostensibly supports the selection of the species subject to the rule. There is also no data suggesting let alone showing that there is a relationship between traceability and the diminution of IUU fishing or seafood fraud. Finally, the record is replete with significant internal inconsistencies including claims by agency personnel of data gaps or data inaccessibility. The agency takes various positions within the rule on its impact economically. At one point, it claims that the rule will not impose measurable incremental costs, but later acknowledges that there will be significant incremental costs associated with the rule especially for complex supply chains.

The analysis under the Regulatory Flexibility Act is similarly flawed, omitting the single largest component of costs, and undervaluing other components. The study cited by the agency suggests that the costs of the Final Rule to consumers and plaintiffs could exceed \$900,000,000 per year. There was no analysis of the economic benefits of the rule, only the legal or psychological benefits. The Final Rule will adversely affect public health by driving up the cost of seafood and, as a result, reducing the consumption of seafood in favor of less healthy sources of protein.

ARGUMENT

I. LEGAL STANDARDS

A. Summary Judgment

The standard for summary judgment is well-established. Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). To make this determination, the court must "view the facts and draw reasonable inferences in the light most favorable to the [non-moving] party." *Scott v. Harris*, 550 U.S. 372, 378 (2007) (citations and internal quotations omitted). A dispute is "genuine" only if a reasonable fact-finder could find for the nonmoving party, and a fact is "material" only if it is capable of affecting the outcome of litigation. *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986). "To defeat a motion for summary judgment, the non-moving party must offer more than mere unsupported allegations or denials." *Dormu v. District of Columbia*, 795 F.Supp.2d 7, 17 (D.D.C. 2011) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986)). The non-moving party must provide affidavits or other evidence setting forth specific facts showing that there is a genuine issue for trial. *Id.*

B. The Administrative Procedure Act

Agency action challenged under the APA shall be set aside when the action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[,]" 5 U.S.C. § 706(2)(A), or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right[,]" *id.* § 706(2)(C). The Court's analysis is limited to the legal rationale presented in the preamble to the proposed and final rules. *See National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 683-84 (2007) ("We have long held, however, that courts may not affirm an agency action on grounds other than those adopted by the agency in the administrative proceedings.") (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)).

C. Regulatory Flexibility Act

Small entities are entitled to judicial review of an agency's RFA analysis. *See* 5 U.S.C. § 611. An agency action may be set aside if it is arbitrary, capricious or an abuse of discretion.

See 5 U.S.C. § 611, *incorporating by reference* 5 U.S.C. § 706(2). Commerce receives no deference for its interpretation of its obligations under the RFA. *See Metropolitan Stevedore Co. v. Rambo*, 521 U.S. 121, 137 n.9 (1997); *Aeronautical Repair Station Ass 'n, Inc. v. FAA*, 494 F.3d 161, 176 (D.C. Cir. 2007) ("[W]e do not defer to the FAA's interpretation of the RFA ... because the FAA does not administer the RFA.").

II. CONGRESS DID NOT AUTHORIZE COMMERCE TO REGULATE SEAFOOD FRAUD

Congress did not authorize Commerce to issue rules to combat seafood fraud. The Final Rule here was an outgrowth of a presidential inter-agency Task Force, which included FDA as well as the Department of Commerce. The Task Force was directed to report to the President "recommendations for the implementation of a comprehensive framework of integrated programs to combat IUU fishing and seafood fraud that emphasizes areas of greatest need." AR 1: Presidential Memorandum Establishing the Task Force. Task Force Recommendations 14 and 15 were to be implemented through the traceability regulations at issue in this case. *See* AR 6908: 81 Fed. Reg. at 88,976 (col. a). Thus, one of the purposes of the Rule was to "ensure that misrepresented products do not enter the U.S. market." AR 6909: 81 Fed. Reg. at 88,977.

That may be a laudable goal, but it is not one that Congress delegated to the Secretary of Commerce. The accurate labeling of food, including seafood, falls within the jurisdiction of the FDA; all rulemaking authority in that area is vested either exclusively in the Secretary of Health and Human Services or, where imported food, including fish, is concerned, jointly in the Secretaries of Health and Human Services and of the Treasury. *See* FDCA §§ 701(a) & 701(b). None is vested in the Secretary of Commerce.⁴ The Secretary of Commerce's rulemaking authority is limited to "illegal, unreported, and unregulated fishing." *See, e.g.*, Illegal, Unreported, and Unregulated Fishing Enforcement Act of 2015, Pub. L. No. 114-81, 129 Stat.

⁴ The original Pure Food and Drug Act of 1906, § 3, vested rulemaking authority in the Secretaries of the Treasury, Agriculture and Commerce. However, Commerce's rulemaking authority was stripped away in subsequent legislation.

649 (Nov. 5, 2015). The Final Rule, though, seeks to cover "seafood fraud," as well as IUU fishing. The Secretary of Commerce has no such rulemaking authority.

A. An Agency May Only Issue Rules that It Is Authorized to Issue

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). "Thus, if there is no statute conferring authority, a federal agency has none." *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001). Commerce has no authority to issue rules governing mislabeling or misbranding of food, including fish. Neither the Proposed Rule nor the Final Rule identifies any such authority, as none exists.

This is not the first time that another agency has sought tread on FDA's jurisdiction. In *Gonzales v. Oregon*, 546 U.S. 243 (2006), the Drug Enforcement Administration, which had been delegated authority under the Controlled Substances Act ("CSA") to regulate narcotics, issued a rule that banned the use of certain narcotics in state sanctioned assisted suicides. The Court held that the Attorney General's rulemaking authority under the CSA was limited to issuing rules relating only to "registration," "control," and "for the efficient execution of his functions" under the statute, and that grant of authority was not sufficient to support a rule effectively banning the use of a drug for a specific purpose. *See Gonzales*, 546 U.S. at 269-70. That jurisdiction rested with the FDA. Here, as in *Gonzales*, Commerce's jurisdiction is limited to combatting IUU fishing. Commerce lacks authority to issue a recordkeeping rule that is either aimed at combatting seafood fraud or that rests on whether a given species is or was likely to be the subject of seafood fraud at some point in the distribution chain. *See Bayou Lawn & Landscape Svcs. v. Secretary of Labor*, 713 F.3d 1080 (11th Cir. 2013) (invalidating a Department of Labor rule because rulemaking authority on that issue had been entrusted to another agency).

B. The MSA Contains No Language Authorizing Commerce to Issue Rules to Regulate Seafood Labeling or Seafood Fraud

"The starting point for [determining the scope of an agency's rulemaking authority is], of course, the language of the delegation provision itself." *Gonzales*, 546 U.S. at 259. Nothing in the MSA or any other statute authorizes the Secretary of Commerce to issue rules with respect to seafood mislabeling. NMFS itself recognized that most of what it wanted to do through the traceability rules was beyond its jurisdiction. Mr. Rauch, who issued both the Proposed and Final Rules, candidly stated:

1. references to IUU and fraud-- Our authority for this rule stems from MSA 307(1)(Q) which prohibits the import, etc. of fish taken or sold in violation of any foreign law or regulation. So clearly this prohibits commerce in "illegal" product. However, it [MSA] does not provide authority for prohibition of unregulated product. It is unregulated so it was not taken or sold in violation of any foreign law or regulation. Similarly, it does not necessarily provide authority for unreported product unless some foreign law or regulation requires reporting. <u>Finally, there is no</u> <u>direct authority for fraud here</u>. The point is that we need to be very careful about what we say is the purpose of this regulation. We cannot say we are doing it to enforce our policy opposition it [sic] [to] the U/U part of IUU or to eliminate seafood fraud.

AR 19459 (Sept. 22, 2015) (emphasis supplied). Commerce's admission here should end the merits portion of this case. *See American Library Ass'n v. Fed. Commc'ns Comm'n*, 406 F.3d 689, 691 (D.C. Cir. 2005).

Congress partially rescued NMFS by enacting two months later the "Illegal, Unreported, and Unregulated Fishing Enforcement Act of 2015," which authorized the Secretary of Commerce to issue regulations to combat unreported and unregulated fishing. Congress did nothing, however, to solve the agency's lack of authority over seafood fraud. That remains so today. It is not enough to suggest, as Mr. Rauch attempted in his September 22, 2015 email, that NMFS's efforts were only directed at IUU fishing, although that action may theoretically have "derivative salient effect on decreasing seafood fraud." AR 19459 (Sept. 22, 2015). The species governed by the Final Rule were selected in part due to "mislabeling concerns." AR 4467-68: 80 Fed. Reg. at 66,870-71 (Oct. 30, 2015). "The list of species at-risk of IUU and seafood fraud

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was determined using principles based on both <u>IUU fishing</u> and <u>seafood fraud</u>. The determination for species was not based on IUU fishing history alone." AR 38459 (emphasis in original). That overreach invalidates the entire rule because the desire to address seafood fraud is inextricably part of the Rule. *See Thorn v. Itmann Coal Co.*, 3 F.3d 713, 718 (4th Cir. 1993) (when a decision relies on several factors, some proper and some improper, the decision must be vacated as "there is no way to know how much of a role [the invalid criterion] had in the final outcome.").

The absence of any authority to regulate seafood labeling or fraud is not something that can be linguistically finessed. The publicly stated purpose of the Rule was to "list of the types of information and operational standards needed for an effective seafood traceability program to combat seafood fraud and IUU seafood in U.S. commerce." AR 14232: Public Presentation by NMFS (Feb. 18, 2016).

Nor can the lack of authority be finessed by resort to the Lacey Act. The Lacey Act provides limited authority other than through FDA to regulate seafood fraud. None of those provisions permits the Secretary of Commerce alone to issue such rules. *See* 16 U.S.C. § 3376(a)(2) ("The Secretaries of the Interior and Commerce shall jointly promulgate specific regulations to implement the provisions of section 3372(b) of this title for the marking and labeling of containers or packages containing fish or wildlife. These regulations shall be in accordance with existing commercial practices.").

While FDA jurisdiction is a matter of law, the facts in the administrative record confirm the wisdom of Congress's decision to house jurisdiction over seafood fraud in the FDA and not in Commerce. For example, NMFS justified including Atlantic Cod as a species at risk for seafood fraud

[g]iven the use of nonspecific tariff codes, there is considerable potential for such generic and ready-to-use cod products to be described, for instance, "Atlantic cod fillets", even if not of Atlantic origin—the sort of misrepresentation that would be precluded by requiring a report on the harvest event.

AR 6916: 81 Fed. Reg. at 88,984 (col. b). No data were presented in the NPRM or Final Rule by NMFS. However, data have been gathered by the one agency with explicit jurisdiction over seafood fraud, namely, FDA. FDA regularly conducts DNA testing of various species to determine whether they have been mislabeled. The result of the DNA testing revealed that all cod samples were properly labeled. Although this information was brought to NMFS's attention, NMFS did not respond. Nor has NMFS explained its belief that linking a specific filet to a specific harvest event would "preclude" seafood fraud even though it now appears from the preamble that there is no intention to require an importer to link a specific filet to a specific harvest event. No data have been presented supporting the notion that any form of the traceability rule, even a robust one, deters miscreants.

III. THE TRACEABILITY RULE WAS ISSUED BY AN EMPLOYEE WHO LACKED RULEMAKING AUTHORITY

Mr. Rauch had no statutory or constitutional authority to promulgate the Final Rule. First, the Secretary's statutory authority to delegate rulemaking does not permit another Officer to re-delegate that authority to Mr. Rauch. Second, even if did permit such redelegation, there is no evidence in the Administrative Record or in the Federal Register that such a multiple level delegation and re-delegation ever occurred here. Third, any attempt to delegate rulemaking to a non-Officer, such as Mr. Rauch, is void because it violates the Appointments Clause.

A. Redelegation of Rulemaking Authority by Another Officer Is Not Authorized

The authority to promulgate the Final Rule is limited to what Congress delegated to the agency. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. at 208; *Gonzales v. Oregon*, 546 U.S. at 258-59. "Rulemaking authority is legislative power" which can only be delegated to an agency by Congress. *Whitman v. American Trucking Ass'n, Inc.*, 531 U.S. 457, 488 (2001) (Stevens, Souter, JJ, concurring) (internal quotations omitted). Similarly, the APA prohibits an agency from issuing a "substantive rule ... except within jurisdiction delegated to the agency and as authorized by law." 5 U.S.C. § 558(b).

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At no time has Commerce referenced any express statutory authority supporting Mr. Rauch's promulgation of the traceability rules at issue here. Nor could it have, as nothing in the MSA authorizes a non-presidentially appointed employee of an agency to issue rules. In the Administrative Record, Mr. Rauch states that the authority to promulgate rules is provided by MSA, Section 307(1)(Q). AR 19459. That provision identifies what activities are prohibited under the Act. It does not authorize Mr. Rauch or someone at his level in the bureaucracy to promulgate rules.

The MSA does authorize the Secretary of Commerce to promulgate rules and it permits a designee of the Secretary to do so, but it does not authorize successive delegations of the sort that would have had to have occurred here. Congress delineated the responsibilities of the Secretary of Commerce in Section 18.55(d), as follows:

The Secretary shall have general responsibility to carry out any fishery management plan or amendment approved or prepared by him, in accordance with the provisions of this chapter. The Secretary may promulgate such regulations, in accordance with section 553 of title 5, as may be necessary to discharge such responsibility or to carry out any other provision of this chapter.

Section 1802(39) defines the term "Secretary" to mean "the Secretary of Commerce or his designee." The Port State Measures Agreement Act of 2015, 16 U.S.C. § 7401 *et seq.*, similarly authorizes the Secretary to promulgate rules and similarly defines the Secretary to include "the Secretary of Commerce or his or her designee." 16 U.S.C. § 7403(a), 7402(7).

Neither the MSA nor the Port State Measures Agreement Act authorizes successive delegations of the duties and powers of the Secretary to an officer or employee of the Department. Where Congress has authorized such successive delegations, it has provided for them explicitly. *See*, *e.g.*, 49 C.F.R. § 322(b) ("The Secretary [of Transportation] may delegate, and authorize successive delegations of, duties and powers of the Secretary to an officer or employee of the Department. An officer of the Department may delegate, and authorize successive delegations of, duties and powers of the officer to another officer or employee of the Department."); 38 U.S.C. § 512(a) ("Except as otherwise provided by law, the Secretary [of

Veterans Affairs] may assign functions and duties, and delegate, or authorize successive redelegation of, authority to act and to render decisions, with respect to all laws administered by the Department, to such officers and employees as the Secretary may find necessary. Within the limitations of such delegations, redelegations, or assignments, all official acts and decisions of such officers and employees shall have the same force and effect as though performed or rendered by the Secretary."); Renegotiation Act, 50 U.S.C. § 403(d)(4) (transferred) ("The Board may delegate in whole or in part any power, function, or duty to the Secretary of a Department, and any power, function, or duty so delegated may be delegated in whole or in part by the Secretary to such officers or agencies of the United States as he may designate, and he may authorize successive redelegations of Authority and Responsibility (Nov. 5, 2002) ("The DEO [Deputy Ethics Official] authority is hereby delegated to each Under Secretary. The Under Secretary, at his or her discretion, may delegate the full DEO authority downward no more than two echelons.").

Thus even if the Secretary's rulemaking authority in this area can be delegated, in the absence of express authorization from Congress, that authority cannot be redelegated, let alone redelegated that far down the chain to an employee at Mr. Rauch's level.

B. The Administrative Record Contains No Notice of any Delegation

The record here contains no proof that the Secretary has delegated her rulemaking authority to NOAA, or NMFS, let alone to a deputy assistant administrator of NMFS, five levels down the organization chart from the Secretary.⁵ Absent such a delegation, any substantive rule issued by Mr. Rauch—or Ms. Sobeck—is invalid *ab initio*.⁶ *See National Ass'n of Waterfront*

⁵ As relevant here, the Department's organization chart indicates that the levels below the Secretary are as follows: (i) Deputy Secretary; (ii) Under Secretary and Administrator of NOAA; (iii) Assistant Secretary; (iv) Assistant Administrator, NOAA (Sobeck) and (v) Deputy Assistant Administrator, NOAA (Rauch).

⁶ Ms. Sobeck was not an inferior officer; she was appointed by Dr. Sullivan when Dr. Sullivan had yet to be confirmed by the Senate. *See <u>http://www.noaanews.noaa.gov/</u>*

Employers v. Chao, 587 F. Supp. 2d 90, 101 (D.D.C. 2008) (invalidating a rule, in part, because the official issuing that rule lacked the delegated authority to do so).

C. The Subdelegation Here Violates the Appointments Clause

The Appointments Clause provides:

[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

U.S. Const. art. II, § 2, cl. 2.

In this way, the Constitution creates three tiers of civil servants: (i) Officers; (ii) inferior officers; and (iii) employees. Officers are appointed by the President with the advice and consent of the Senate. Inferior officers are appointed by the President without the advice and consent of the Senate, by the Courts, or by heads of departments. Employees are those employed by the Executive Branch who are neither officers nor inferior officers. Each type of employee is permitted to exercise certain types of authority with Officers exercising ultimate governmental authority.

In evaluating whether the Appointments Clause has been violated, courts first assess whether the civil servant exercised the type of significant authority normally associated with "Officers." If such is the case, then the court will examine whether the individual was appointed by the President with the advice and consent of Senate. If not, then the civil servant is exercising authority beyond his station and that exercise is void *ab initio*. The first question is usually complex analytically because it requires parsing the type of authority being exercised by the civil servant. Here, no such detailed analysis is required. The Supreme Court has consistently held that rulemaking is one of those quintessential authorities that can exercised only by "Officers"

stories2014/20140115_sobeck.html and http://www.noaa.gov/kathryn-sullivan-confirmed-noaa-administrator.

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primarily because it represents a form of ultimate governance--combining legislative and executive authorities. *See Buckley v. Valeo*, 424 U.S. 1, 141 (1976). Thus, when the Court invalidated the composition of the Federal Election Commission on Appointments Clause grounds, one of the factors relied upon by the Court in concluding that the Commissioners were Officers was their rulemaking authority. *Id.* ("These administrative functions [including rulemaking] may therefore be exercised only by persons who are "Officers of the United States.").

Therefore, even if the MSA authorized the Secretary to delegate her rulemaking authority to an Officer who was further authorized to redelegate it to an inferior officer, the delegation to an inferior officer, let alone an employee, would be in contravention of the Appointments Clause and without effect. *See Freytag v. Commissioner*, 501 U.S. 868, 881 (1991) (rejecting the argument that special trial judges of the Tax Court are employees rather than officers because "they lack authority to enter a final decision"); *Raymond J. Lucia Cos., Inc. v. SEC*, 832 F.3d 277, 283 (D.C. Cir. 2016) (holding that SEC ALJs are employees because they cannot lawfully render final decisions). *Cf. Bandimere v. SEC*, 844 F.3d 1168, 1188 (10th Cir. 2016) (finding SEC ALJs are inferior officers subordinate to the SEC commissioners, but declining to answer questions about rulemaking or other potential consequences of its conclusion).

This is precisely what occurred here. The organization chart for both Commerce and NOAA discloses that the office that Mr. Rauch held, deputy assistant administrator for regulatory programs at NMFS, is five tiers down from the Secretary of Commerce. *See* https://www.commerce.gov/sites/commerce.gov/files/media/files/2015/docorgchartfinal.pdf (commerce organization chart); http://www.noaa.gov/about/organization (NOAA organization chart). It is not a position that requires Senate approval. *See* Congressional Research Service, Presidential Appointee Positions Requiring Senate Confirmation and Committees Handling Nominations at 15 (Aug. 23, 2016), available at https://fas.org/sgp/crs/misc/RL30959.pdf Neither is the NMFS Assistant Administrator a Senate-confirmed position. Thus the rule issued

by Mr. Rauch or even by his superior Ms. Sobeck violates the Appointments Clause and is void *ab initio*.

IV. DEFENDANTS VIOLATED THE ADMINISTRATIVE PROCEDURE ACT

A. Secret Rulemaking Is Not Permitted Under the APA

The APA generally obliges an agency to publish for comment the technical studies and data on which it relies. *See* 5 U.S.C. § 553(b)(3) (notice of a proposed rule must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved."). *See also Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) (*per curiam*). In the D.C. Circuit, "[a]n agency may not keep secret evidence on which it intends to rely to support its decision." *Ethyl Corp. v. Envtl. Prot. Agcy.*, 541 F.2d 1, 87 n.82 (D.C. Cir. 1976). *See also Chamber of Commerce v. SEC*, 443 F.3d 890, 899 (D.C. Cir. 2006) ("Among the information that must be revealed for public evaluation are the 'technical studies and data' upon which the agency relies [in its rulemaking].") (citation omitted). The reason for this requirement is obvious. Construing section 4 of the APA, the D.C. Circuit explained long ago that "[i]n order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules." *Conn. Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982).

Here, the underlying data used to support Mr. Rauch's determination were not presented either in the Federal Register notice issued on October 30, 2015, in the proposed rule or in the Final Rule. Instead, the agency has taken the position that

> [d]etailed presentation of the data considered by the Working Group and its deliberations is protected from disclosure because of data confidentiality and enforcement implications.

AR 4467: 80 Fed. Reg. at 66,870 (col. a). The failure to produce the underlying data effectively precludes meaningful public comment. This is similar to the actions of the FCC in *American Radio Relay League, Inc. v. FCC*, 524 F.3d 227 (D.C. Cir. 2008), where the agency initially

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failed to produce its studies and ultimately provided them, in redacted form, under a FOIA request and augmented the administrative record with those redacted studies. The Court concluded that "[i]t would appear to be a fairly obvious proposition that studies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment." *Id.* at 237. The Court then observed with respect to redaction that "[w]here, as here, an agency's determination is based upon a complex mix of controversial and uncommented upon data and calculations, there is no APA precedent allowing an agency to cherry-pick a study on which it has chosen to rely in part." *Id.* (internal quotation marks omitted). In the end, the Court remanded and ordered the FCC to place unredacted studies in the administrative record for public analysis and comment.

Here, the agency refused to put into the public record the studies and data on which it relied to identify the species subject to this rule. Plaintiffs have been prejudiced by the absence of these data. As stakeholders, they have relevant information regarding the selection of species subject to the rule and may have credibly challenged the selection if they had been given the opportunity to comment on the data relied upon by the agency. Without the disclosure of the data, plaintiffs have been denied the ability to assess the strengths and weaknesses of the conclusions.

The agency's reliance on secret data also limits the agency's ability to support its rules with materials in the administrative record. The propriety of the rules and whether they are arbitrary and capricious is determined with respect to the administrative record. Where, as here, the agency has not identified let alone examined the relevant data and explained its action or provided a "rational connection between the facts found and the choice made," the Court may set aside the agency's action as arbitrary or capricious. 5 U.S.C. § 706(2)(A). *Motor Vehicle Mfgs. Ass 'n*, 463 U.S. at 43; *Owner-Operator Indep. Drivers Ass 'n v. Federal Motor Carrier Safety Admin.*, 494 F.3d 188 (D.C. Cir. 2007). The court must be able to discern the connection between the facts relied on and the choices made from the record and the agency decision. *See City of Brookings Mun. Tel. Co. v. FCC*, 822 F.3d 1153, 1165 (D.C. Cir. 1987). "[T]he function

of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." Styrene Info. & Research Ctr., Inc. v. Sebelius, 944 F. Supp. 2d 71, 77 (D.D.C. 2013); see Mashack v. Jewell, No. 15-2107 (D.D.C. Feb. 26, 2016) ("Under the APA, it is the agency's responsibility to resolve the factual issues and arrive at a decision that is supported by the administrative record, and the court is left to 'determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did."") (quoting Occidental Eng'g Co. v. INS, 753 F.2d 766, 769-70 (9th Cir. 1985), and citing Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971) and Richards v. INS, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977)); see also Ronald M. Levin, "Vacation" at Sea: Judicial Remedies and Equitable Discretion in Administrative Law, 53 DUKE L. J. 291, 294 n.5, 298 n.20 (2003) (citing Fed. Power Comm'n v. Transcon. Gas Pipe Line Corp., 423 U.S. 326, 331 (1976)) (holding that agency decisions not supported by the administrative record must be vacated). That explanation cannot be supplied after the fact. National Coalition Against the Misuse of Pesticides v. Thomas, 809 F.2d 875, 883 (D.C. Cir. 1987) (rejecting "a post hoc rationalization ... to buttress agency action.").

Without those data, there is no basis in the administrative record to support the selection of the specific species to be governed by the rules, making the rules arbitrary and capricious. *See* 5 U.S.C. § 706(2)(A); *United Steel, Paper and Forestry, Rubber, Mfg., Energy, Allied Indus. and Serv. Workers Int'l Union v. Federal Highway Admin.*, 151 F. Supp. 3d 76 (D.D.C. 2015) (holding a rule is arbitrary and capricious where there was "nothing in the administrative record indicat[ing] why 90 percent is a superior threshold to 80 percent or 70 percent or 60 percent."). The Final Rule should be vacated for this reason.

More fundamentally, there are no data in the administrative record showing a relationship between a traceability program and a reduction in IUU fishing or seafood fraud. As one NOAA official noted in an internal memorandum, "[w]hat verification scheme would show whether or not fish was a product of illegal fishing? In other words, a box of shrimp from Thailand is

offloaded by ship in NY. All the paperwork is complete and accurate. What would tell us that the shrimp was (or was not) taken in violation of foreign law?" AR 53521.

B. The Rule is Arbitrary and Capricious Because It Is Internally Inconsistent and Based on Studies that Do Not Support the Rule

A regulation that is internally inconsistent or lacks a sound basis in reason and data is, by definition, arbitrary and capricious within the meaning of APA § 10, 5 U.S.C. § 706. *See Bus. Roundtable v. SEC*, 647 F.3d 1144, 1153–54 (D.C. Cir. 2011) (vacating a rule that lacked datum on a crucial assumption and was based on a discussion that was "internally inconsistent and therefore arbitrary"). Thus, this Circuit has "often declined to affirm an agency decision if there are unexplained inconsistencies in the final rule." *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015); *see also Gulf Power Co. v. FERC*, 983 F.2d 1095, 1101 (D.C. Cir. 1993) ("[W]hen an agency takes inconsistent positions ... it must explain its reasoning."); *Gen. Chem. Corp. v. United States*, 817 F.2d 844, 846 (D.C. Cir. 1987) (holding agency action to be arbitrary because its analysis was "internally inconsistent and inadequately explained").

1. The Agency's Cost Assessments Are Internally Inconsistent and Inconsistent with the Study Relied upon by the Agency

This Rule is like a "a horse designed by committee," and is rife with significant internal inconsistencies and statements that are based on speculation and devoid of factual support. More is required. The agency "had a duty here to examine and justify the 'key assumptions' underlying its decision, and it failed to do so." *United States Sugar Corp. v. Envtl. Prot. Agency*, 830 F.3d 579, 650 (D.C. Cir. 2016) (citing *Appalachian Power Co. v. EPA*, 135 F.3d 791, 818 (D.C. Cir. 1998) ("EPA retains a duty to examine key assumptions as part of its affirmative burden of promulgating and explaining a nonarbitrary, non-capricious rule.") (internal quotation marks omitted).

First, the agency's assessment of how much its Rule will cost the seafood sector to implement is internally inconsistent. The agency received comments from plaintiffs, among others, who import seafood that processors and harvesters will charge seafood importers to

collect the data necessary for importers to comply with this Rule and this will in turn drive up the cost of seafood. In the preamble, the agency sidesteps this concern by stating, without the benefit of any data, that

NMFS does not agree that harvesters and farmers will be in a position to demand payment for traceability data, and commenters did not provide quantitative information regarding the likelihood of such risks. There is no indication that the imposition of existing catch documentation systems (*e.g.*, the EU system) resulted in measurable increases in the cost of seafood."

AR 6917: 81 Fed. Reg. at 88,985 (col. c), quoted in Complaint at ¶ 73a.

There are three problems with this assertion. First, it is inconsistent with the results of a study relied upon by the agency in its Final RFA analysis. That study, which assessed the costs associated with the MSC traceability program in Sweden, concluded that the prices for fish in Sweden increased by ten percent as a result, which is not only measurable, but also significant and inconsistent with the agency's statement that "[t]here is no indication that the imposition of existing catch documentation systems (*e.g.*, the EU system) resulted in measurable increases in the cost of seafood." *See* AR 6935, 6939: Final RFA at 5 n.6 & 9 (citing Blomquist, J., *et al.*, *Price Premiums for Providing Eco-labelled Seafood: Evidence from MSC-certified Cod in Sweden*, 66 J. AGRICULTURAL ECON. 690-704 (2015). The study is also inconsistent with the statement in RFA analysis that compliance costs would only be one percent. It is difficult to fathom what happened to remaining nine percent between the Final Rule and its RFA analysis.

Second, the statement is inconsistent with statements in the preamble where the agency acknowledges that chain of custody costs in complex systems "may be either passed through to U.S. consumers or result in a decline in exports to the U.S." *See* AR 6918: 81 Fed. Reg. at 88,986. These costs are especially relevant given that one of the factors used in determining whether to subject a species to the rule was the complexity of its distribution chain: the more complex, the greater the likelihood of being listed as a "priority" or "at-risk" species. *See* AR 4465: 80 Fed. Reg. at 66,868. One would therefore expect that the at-risk species would be those

with complex distribution chains and the regulation, by definition, would have a greater cost impact on those species than on those with less complex chains.

Third, the agency's statement that there would be minimal to no costs or price increases associated with the rule is not the result of any independent assessment, but rather nothing more than an assumption that appears to be inconsistent with the results of the Swedish study relied upon by the agency. See AR 6938: Final RFA Analysis at 8. In situations such as this, where pivotal assumptions underlying an agency's rulemaking are inconsistent with studies relied upon by the agency in the rulemaking, the courts have been quick to invalidate the rule. Medicare's Malpractice Rule is a case in point. That rule sought to allocate a hospital's malpractice insurance costs based on a study that allegedly showed that malpractice costs associated with treating older Americans, e.g., those on Medicare, were much lower than the corresponding costs for younger Americans. The study cautioned that its conclusions could not be generalized because the study did not distinguish between hospital and physician malpractice awards. Despite this admonition from the study's authors, Medicare used the study as the basis for its regulation. Scores of district courts and seven circuits invalidated the rule as inherently arbitrary. See, e.g., Cumberland Med. Ctr. v. Sec'y of HHS, 781 F.2d 536 (6th Cir. 1986); Bedford County Mem'l Hosp. v. HHS, 769 F.2d 1017 (4th Cir. 1985); Menorah Med. Ctr. v. Heckler, 768 F.2d 292 (8th Cir. 1985); Desoto Gen. Hosp. v. Heckler, 766 F.2d 182, as amended at 776 F.2d 115 (5th Cir. 1985); Lloyd Noland Hosp. and Clinic v. Heckler, 762 F.2d 1561 (11th Cir. 1985); St. James Hosp. v. Heckler, 760 F.2d 1460 (7th Cir.), cert. denied, 474 U.S. 902 (1985); Humana of Aurora, Inc. v. Heckler, 753 F.2d 1579 (10th Cir.), cert. denied, 474 U.S. 863 (1985); Abington Mem'l Hosp. v. Heckler, 750 F.2d 242 (3d Cir. 1984), cert. denied, 474 U.S. 863 (1985). Ultimately the malpractice rule was withdrawn, re-issued, and struck down. See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204 (1988) (invalidating the re-issued rule as unauthorized retroactive rulemaking). Here, NMFS has relied on a study that undermines the agency's analysis without addressing that discrepancy.

2. The Agency Claims that Its Rule Is Based on Evidence But None Is Cited and It Is Possible that None Exists

a. The Agency Admits that It Has No Evidence Concerning Seafood Fraud

Throughout the rulemaking, the agency claimed that it selected the at-risk species based, in part, on the extent that a given species is the subject of seafood fraud. In the introduction to the preamble, the agency asserts that the final rule applies to species "identified as being at particular risk of illegal, unreported, and unregulated (IUU) fishing or seafood fraud[.]" AR 6907: 81 Fed. Reg. at 88,975 (col. b). The agency then claims that "evidence exists that aquaculture products have been subject to various types of product misrepresentation, some of which can cause risk to human health." AR 6909: 81 Fed. Reg. at 88,977 (col. b). The two principle criteria used by the agency to identify species prone to seafood fraud were

[t]he history of known misrepresentation of a species related to substitution with another species, focused on mislabeling or other forms of misrepresentation of seafood products. . . . [And] [t]he history of known misrepresentation of information other than mislabeling related to species identification (*e.g.*, customs misclassification or misrepresentation related to country of origin, whether product is wild vs. aquaculture, or product weight).

AR 4466: 80 Fed. Reg. at 66,869 (Oct. 30, 2015). The agency's confident prose contrasts sharply with the tone of the agency's internal memoranda, which reveal that there was "no there there." Gertrude Stein, EVERYBODY'S AUTOBIOGRAPHY (1937). When one agency employee requested data on seafood fraud, she was advised that "[w]e don't track 'fraud' per se. We have FDA referrals, which are mostly decomposition and none referred recently for mislabeling or short weight." AR 32019 (May 5, 2015). Various other offices and regions within NOAA were then queried about whether they maintained seafood fraud data. The Southeast Region stated: "The SE Region does not have a tracking system in place for seafood fraud data." *Id.* Another office responded that "[w]e have no fraud data in the Hampton, VA, supervisory area." AR 32018. The agency had originally planned on using data on imports by species to help select the at-risk species. But even here it learned that basic information did not exist. As one employee

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noted, "there may be complications [in attempting to ascertain imports by species], most importantly the fact that most products are not reported to the species level." AR 23942 (June 11, 2015). The same NOAA employee stated earlier that "[t]here are a couple of complications with the import data that will make it difficult to give you 'clean' answers. First, most products in the trade data are not specified to the species level." AR 23943 (June 8, 2015). Recognizing that it lacked any data on seafood fraud even though it figured prominently in selecting at-risk species, the agency turned to private distributors. One agency employee suggested

that Kroger, one the programs largest customers, does periodic DNA testing. I'm not sure if this is fraud detection or not but it may be helpful to know. I feel like it is a check to make sure they are buying the correct spicies [sic]. This [is] a total Kroger effort. We simply pull the samples from product we inspect for Kroger. Call if I can help.

AR 32018 (May 6, 2015). NOAA asked Kroger if it would be willing to share the results of its DNA testing with NOAA. Kroger declined. AR 32017 (May 7, 2015) ("they will not release their results.)."

This is troubling on two levels. Aside from evidencing an absence of any data with respect to seafood fraud, it shows that the agency was either unaware or ignored that DNA testing is used to confirm the identity of species as a way of avoiding seafood fraud and therefore, failed to consider it as a viable, less costly, option for combatting seafood fraud. These errors are exacerbated by the agency's apparent failure to consult seafood sampling done by FDA in recent years. For example, NMFS deemed Atlantic cod "at risk" because of supposed species substitution. But when FDA conducted DNA testing of cod at the import and wholesale level, 100% of the cod samples tested were labeled properly. *See* FDA DNA Testing at Wholesale Level to Evaluate Proper Labeling of Seafood Species in FY 12-13, available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ Seafood/ucm419982.htm).⁷

⁷ Ignoring this science, the agency informed at least one major Atlantic cod-producing nation that this fish was to be included within the scope of the Final Rule because of evidence of

b. The Agency Misreported Paperwork Reduction Act Costs in Its NPRM

Not only did the agency appear to operate in a data vacuum, when it did have data it misreported them thereby undermining the credibility of the rulemaking. For example, as part of its Paperwork Reduction Act analysis in the NPRM, the agency reported that "the information collection burden . . . applicable to imports of the designated at-risk species are estimated to be an increase of 18,542 hours and \$278,130." AR 4487-88: 81 Fed. Reg. at 6220-6221. However, in its Paperwork Reduction Act submission to OMB, the agency estimated that the proposed rule's "[a]nnual recordkeeping and reporting burden" would total 189,317 hours, or about 10 times the amount listed in the NPRM, and the total cost, as submitted to OMB, was listed as \$5,093,000, about 20 times what was listed in the NPRM. AR 20977. It should be noted that the agency submitted another Paperwork Work Reduction Act Analysis to OMB for the proposed rule where the annual burden in hours was about 20 times the number listed in the NPRM and the costs were about 4 times what was listed in the NPRM. *See* AR 19126. Since neither document is dated, one cannot ordain which was filed earlier. Irrespective of which analysis was last filed with OMB, neither analysis is reflected in the NPRM.⁸

This merely confirms that the agency itself was attempting to make policy without the benefit of its own data and when its own data existed, those data were not accurately reported. An inability to accurately report data is particularly significant where, as here, the unidentified data underlying the substantive aspects of this rule were obtained from unidentified third parties who collected the data in an unidentified manner. Playing telephone with rulemaking, as is the case here, is perilous especially where neither the first nor the last person in the chain has proven proficient at accurately reporting information in related contexts. *See Suntharalinkam v. Keisler*,

mislabeling occurring in the United States. AR 29128. But the Final Rule could not possibly remedy such mislabeling, as the Rule does not apply to seafood post-importation.

⁸ The Final Rule adopted a higher annual cost of \$7,875,000 in the first year, and, based on comments, an upper limit of \$20,315,225. AR 6926: 81 Fed. Reg. 88,994. This belated attempt at correction still is inaccurate.

506 F. 3d 822, 831 n.9 (9th Cir. 2007) ("As we know from playing 'Telephone,' the longer the communication chain, the more likely there is to have been a misunderstanding.").

c. The Agency Was Not Forthcoming With Respect to Aquaculture Data

The preamble states that "NOAA agrees that IUU fishing is not a concern directly related to the aquaculture industry." AR 6909: 81 Fed. Reg. at 88,977 (col. b). The Agency goes on to conclude, though, that subjecting the aquaculture industry to this Rule is appropriate for a number of reasons including that "evidence exists that aquaculture products have been subject to various types of product misrepresentation, some of which can cause risk to human health." *Id.* None of this so-called evidence appears in the rulemaking record, and as discussed below, regulating labeling falls outside of NOAA's jurisdiction. According to the agency, regulation of aquaculture seafood is also proper because,

similar to wild capture fisheries, aquaculture operations are likely to be subject to foreign laws or regulations pertaining to licensing and reporting on production and distribution; importation of aquaculture products harvested in violation of those laws would make them subject to the MSA provision under which this rule is promulgated.

Id. This is a statement of law, but it does not address the more fundamental issue of whether seafood raised through aquaculture are as at risk for mislabeling as seafood caught in the wild. No evidence is presented in support of the agency's proposition.

Extending the rule to include aquaculture seafood highlights another anomaly. Throughout the rulemaking, the agency has argued that those that already import into the EU should not face increased incremental costs. Specifically, the agency stated that

> [t]here is no indication that the imposition of existing catch documentation systems (e.g., the EU system) resulted in measurable increases in the cost of seafood. The harvest event data required to be provided under the U.S. program aligns very closely with those data on the harvest event required in the European Union catch certification program.

AR 6917: 81 Fed. Reg. at 88,985 (col. c). The agency failed to "[n]ote that the EU program focuses on marine capture fishery products, thus freshwater fish and products of aquaculture

operations are excluded." AR 19334. This statement appeared in a proposed response to comments that never made it into the Federal Register version. The omission is significant because it undermines the agency's claim that the costs of EU program and U.S. program ought to be the same. There are a variety of reasons that this is not the case, but a significant reason is that the Final Rule governs a much larger group of seafood than the EU rule, *i.e.*, wild caught, aquaculture, fresh water (Final Rule) vs. wild caught only (EU Rule).

d. The Agency Has Failed to Present Any Data Concerning Various Species

With respect to both Atlantic and Pacific Cod, as examples, NMFS acknowledges that IUU fishing is "not widespread." R 6916: 81 Fed. Reg. at 88,984 (col. b). It included the species in the Rule because, among other reasons, "there have been reports to NOAA of illegal fishing of both . . . species." *Id.* The nature, number or source of these reports is not revealed. There is thus no way to assess the validity of those reports relied upon by NOAA. This is a critical aspect of the rulemaking process, especially here, where those in the agency had concerns about the integrity of data underlying various decisions. For example, one NOAA employee, when discussing seafood fraud stated that "[f]or blue crab, I don't know the extent of confusion/mislabeling etc. I just know that I've had some questions where people questioned what was in the official Census trade data. For red snapper I probably overstated the case." AR 22274 (April 11, 2016). Despite having overstated the case, red snapper remained on the list of at-risk species.

3. The Agency Hid Facts Showing that the Compliance Date It Selected Would Cause Tens of Millions of Dollars of Seafood to Become Unusable

The agency set January 1, 2018, as the compliance date and urged that

[f]or products harvested prior to the compliance date, U.S. importers should work with their foreign suppliers to ensure that the harvest event and supply chain records are available for any entries made on or after January 1, 2018. AR 6920: 81 Fed. Reg. at 88,988 (col. c). During the interregnum between the effective date (January 9, 2017) and the compliance date (January 1, 2018), NOAA would be developing and testing the electronic systems that would be used by importers to input the data required by the Rule. Those systems do not exist today. The Rule's timing and the absence of time travel create an expensive set of problems that the agency appears to have intentionally ignored, namely that large quantities of seafood were caught domestically and exported before the Final Rule was issued and will not reenter the United States until after the compliance date. In short, there is long lag time between harvest in the United States and re-importation. In an internal memorandum, NOAA acknowledges that

[w]hile we are considering an implementation date 12 months from publication, importers cannot immediately come into compliance on that date. Importers will have to anticipate that entries after the effective date (which were harvested prior to the effective date) must be transported with the data on the harvest event.

AR 20256 (Sept. 8, 2016).

One NOAA employee, recognizing this issue, suggested in an internal memorandum that the rule only apply to "fish harvested on a fishing trip that began on or after 60 days . . . after the FR publishing date." AR 20257. This would have been a rational option for dealing with fish harvested and exported from the United States before the Rule was published. This suggestion was rejected without apparent discussion or reason even though the current compliance date will cost domestic fishermen tens of millions of dollars in fish that cannot be re-imported because of the absence of any pedigree documents. These costs were not discussed in the rulemaking and were not evaluated as part of the RFA analysis. As to those fish, the Rule is not only irrational but effectively retroactive in violation of *Bowen v. Georgetown Hosp.*, 488 U.S. 204. Moreover, effective implementation, as the agency acknowledges, requires the agency to publish "compliance guidance as well as a 'plain language' description of the final regulation." AR 6915: 81 Fed. Reg. at 88,983 (col. c). None of this has occurred, making timely implementation that much more difficult.

V. NMFS Failed to Perform the Analysis Required under the RFA

Small entities are entitled to judicial review of an agency's RFA analysis. *See* 5 U.S.C. § 611. In enacting the RFA, 5 U.S.C. §§ 601-612, as amended by the Small Business Regulatory Enforcement Fairness Act ("SBREFA"), Pub. L. No. 114-121, Title II, 110 Stat. 847, 857-74, §§ 201-253 (1996), Congress expressly recognized that agency rules frequently had a disproportionate adverse impact on small businesses, not-for-profit organizations, and small governmental entities. These entities face practical difficulties in complying with federal rules that differ significantly from those encountered by their larger counterparts, including "their limited access to capital," that "small concerns must borrow heavily to make modifications[,]" and that costs of complying cannot be easily absorbed or spread by small entities as they can by larger entities. S. Rep. No. 878, 96th Cong., 2d Sess. 4 (1980). Small entities lack access to the equity markets and "[e]ven if small businesses can afford additional debt, banks and other lenders are often reluctant to loan money for improvement purposes not related to productivity." *Id.* This lack of access to financing--whether debt or equity--has become particularly acute since the onset of the recession in September 2008, and has only worsened since then.

In the RFA, Congress therefore required agencies, as part of the rulemaking process, to conduct initial and then final regulatory analyses to ascertain the economic impact that a putative rule will have on small entities, to set out the less onerous alternatives considered by agency, and to discuss the agency's rationale for declining to adopt these less costly alternatives. *See* 5 U .S.C. §§ 603-604. There is no dispute that the RFA applies here. *See* AR 6926: 81 Fed. Reg. at 88,994

In this case, NMFS failed to conduct a proper regulatory flexibility analysis of its Final Rule. First, NMFS failed to take into account the most significant cost component of the Final Rule—the costs of the change in which seafood must be processed overseas in order to preserve traceability data required under the Final Rule as well as the cost of the loss of fish harvested and exported before the Final Rule was published, but re-imported after January 1, 2018. *See* pages 32-33, *supra*. These costs pale in comparison to the data entry costs which NMFS understated.

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Omission of a category of costs or using an incorrect methodology to ascertain a class of costs is grounds for remand. *See S. Offshore Fishing v. Daley*, No. 97-1134-CIV-T-23C (M.D. Fla. Oct 16, 1998); *N. Carolina Fisheries Ass'n, Inc. v. Daley*, 27 F. Supp. 2d 650 (E.D. Va. 1998).

Many commenters highlighted this omission in the initial RFA analysis. Rather than rolling up their sleeves, examining the data and doing an appropriate assessment of these costs, NMFS chose to bury them under a bunch of words. See AR 6951: Final RFA Analysis at 21 ("NMFS acknowledges that there will be incremental costs; it just could not quantify them."). NMFS had European data from which could have been extrapolated to this Rule. After all, NMFS has taken the position that its rule would not impose significantly more burdens on importers than are already in place under the EU or EU-like systems. AR 6937: Final RFA Analysis at 7 ("Thus it can be expected that compliance with the U.S. reporting requirements would not be a significant burden for exporters already compliant with the E.U. program."). The costs associated with any traceability system are staggering, as noted in the study cited by NMFS itself. AR 6935: Final RFA Analysis at 5 n.6 (citing Blomquist, J., et al., Price Premiums for Providing Eco-labelled Seafood: Evidence from MSC-certified Cod in Sweden, 66 J. AGRICULTURAL ECON. 690-704 (2015). That study stated: "MSC certification is costly, ranging from \$ 35 000 for small-scale fisheries to almost \$ 350 000 for large industrial fisheries ... There are also additional costs for pre-assessment, annual audits, and costs associated with the implementation of improvements to address the conditions placed on the fishery during the certification process certification." (citation omitted). Based on this data and NMFS's calculation that there are approximately 2,000 importers and 600 entry filers, all considered to be small entities subject to the rule (AR 6951-52: Final RFA Analysis at 21, 22), the cost of the certifications under the Final Rule would range from \$91,000,000 to \$910,000,000, depending on the size of the companies involved. The Final Rule is broader, and necessarily more costly, than the MSC certification process, covering aquaculture as well as wild-caught products. These numbers are consistent with the incremental costs of ten percent experienced under the MSC program. The Final RFA analysis estimates total imports of \$9 billion for the species subject to

the Final Rule. *See* AR 6952: Final RFA Analysis at 22. Ten percent of that figure is \$900,000,000. *See* Final RFA Analysis at 22. This was the elephant in the room that NMFS wants everyone to ignore.

NMFS disputed the conclusions of the commenters who pointed out that the agency had failed to figure in the cost of paying harvesters and farmers for traceability data, the cost of auditing suppliers, insuring themselves against the risk of erroneous information or the related risk of delayed entry of imports. AR 6949: Final RFA Analysis at 19. On the theory that the best defense is a good offense, NMFS charged that the commenters had not provided qualitative or quantitative information regarding the likelihood of such risks even though NMFS itself had that information at its fingertips and even though it is the agency's, not the public's, responsibility to meet the RFA's analytical requirements. AR 6935: RFA Analysis at 5 n.6 (citing Blomquist, *supra*).

NMFS similarly disputed the remaining additional costs, either claiming unfamiliarity with the concepts raised or simply disagreeing with the conclusions. Ignorance is not bliss when it comes to the agency's obligations under the RFA. *See Aeronautical Repair Station Ass'n, Inc. v. FAA,* 494 F.3d 161 (D.C. Cir. 2007) (finding the agency failed to discharge its obligations under the RFA by ignoring the practical effect of its rule on the regulated population). NMFS touts that it clarified the requirements for reporting on multiple harvest events contributing to a single shipment, but ignores that its assumption, reflected in both the preamble and the RFA analysis, that a processor would not have to segregate harvest events during processing in order to preserve traceability data is not accurate. AR 6908-09: 81 Fed. Reg. at 88,976-77. Under the Final Rule, as explained in the preamble, NMFS contemplates that a single 44,000 pound container of fish or seafood would merely need to list all of the harvest events for all of the seafood in that container without relating any given harvest event to any specific piece of seafood. Even if this were so, it does not obviate the need for a processor to segregate and maintain harvest identity of seafood during processing which is a significant cost. Multiple orders for multiple customers are processed simultaneously, necessarily requiring them to

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segregate and maintain harvest identity by importer of the seafood during processing. Exh. E: Decl. of John P. Connelly at ¶ 9. Moreover, as in *Aeronautical Repair Station Ass'n*, the agency cannot claim that it does not have to take into account the cost to entities directly affected by the Final Rule, such as grocery stores, or restaurants.

As for alternatives, here too, the agency's analysis was deficient. NFMS considered only three alternatives: (1) no action; (2) collecting harvest event data and supply chain image files; and (3) collecting a limited electronic data set requiring no scanned documentation. AR 6953-54. NMFS declared that the first option did not discharge its obligation to implement the Presidential Task Force's recommendations or an Executive Order on streamlining the exportimport process or the SAFE Port Act. AR 6954: Final RFA Analysis at 24. The second two options, according to NMFS, imposed too great a cost or unnecessary burdens on the private sector and the government. Id. NMFS was aware of, but did not consider a fourth alternative-developing new or adapting existing technologies to better identify and track IUU fishing. In an undated document, entitled "Key Messages," NMFS noted that technology presented an opportunity to combat IUU fishing. It stated: "One of these tools is SeaVision, a product that leverages Google Maps, displaying more than 62,000 ships around the world and their corresponding information." AR 29565. Nor did NMFS consider DNA testing as a way of combating seafood fraud (assuming it had jurisdiction) even though the agency was aware of it. See AR 32018. Consideration of alternatives here was a hollow gesture when the agency stacked the deck in favor of the desired outcome.

VI. The Secretary Failed to Conduct a Cost-Benefit Analysis Required by Executive Order 12866

A. The Secretary's Cost-Benefit Analysis Is Incomplete

The MSA, § 305(e), 16 U.S.C. § 1855(e), requires the Secretary, in issuing rules, to comply with the requirements of Executive Order 12866. That Executive Order applies fully to "significant rules" and requires the agency to assess "the potential costs and benefits of the

regulatory action."⁹ The agency has determined that this is a "significant rule," under the Executive Order. *See* AR 6925: 81 Fed. Reg. at 88,993 (col. b). Nonetheless, the agency failed to start or complete the cost-benefit analysis required by the Executive Order.

The Executive Order cautions agencies that

agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider.

Executive Order 12866, § 1(a), 58 Fed. Reg. 51,735 (Oct. 4, 1993). The purpose of the Executive Order was to ensure that the regulatory alternative selected by the agency was largely data driven and that "in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits." *Id.* To measure the benefit of the rule, the agency would have had to have assessed the impact on IUU fishing of the proposed rule. This it could have done by assessing the impact of the EU traceability rule on IUU fishing, or by developing a valid mathematical model. The agency, though, made no attempt to do either. As a result, the record is devoid of any attempt by the agency to measure or even qualitatively assess the impact that its reporting rule would have on deterring IUU fishing. Therefore, where the benefit side of ledger is missing, as is here, it is impossible to assess the net benefits of the rule, *e.g.*, benefit less costs. Yet, this is precisely what the Executive Order requires the Secretary to do.

The cost analysis performed under both the Executive Order and the RFA is infirm for the reasons set forth in plaintiffs' discussion of the RFA analysis.

⁹ Ordinarily, the Executive Order does not provide a private right of action. However, here its requirements as they pertain to the Secretary have been enacted into positive law and therefore, afford a private right of action under section 10 of the APA.

B. The MSA and the APA Create a Private Right of Action Under Executive Order 12866

Normally, agencies pay scant attention to Executive Order 12866 because, standing alone, it arguably has no effect on "otherwise available judicial review of agency action." Section 10 of the Executive Order provides as follows:

> Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Courts have interpreted this language, standing alone, as creating no private right of action. *See Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 9 (D.C. Cir.1999). However, that is not the case here. Section 305(d) of the MSA authorizes the Secretary to "promulgate regulations, in accordance with section 553 of title 5, as may be necessary to discharge such responsibility or to carry out any other provision of this chapter [16 U.S.C. §§ 1801-1891]." The illegal fishing provision relied on by the agency is at § 1857(1)(Q). The following subsection affirmatively incorporates the requirements of the Executive Order:

The Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.),[1] the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), and <u>Executive Order</u> <u>Numbered 12866</u>, dated September 30, 1993, shall be complied with within the time limitations specified in subsections (a), (b), and (c) of section 1854 of this title as they apply to the functions of the Secretary under such provisions.

16 U.S.C. § 1855(e) (MSA § 305(e) (emphasis supplied).

This provision transforms an Executive Order, which may or may not have the force and effect of law, into positive law, imposing an obligation on Commerce to conduct a cost-benefit analysis. If, as here, an agency issues a regulation without complying with the analytical requisites of the Executive Order as incorporated into the MSA, then the rule was issued "not in accordance with" with the MSA. 5 U.S.C. § 706(1)(A). Rules issued in contravention of an agency's organic legislation are subject to judicial review, normally under APA § 10.

VII. THE FINAL RULE SHOULD BE VACATED WITH RESPECT TO THE APA VIOLATIONS AND ENJOINED AND REMANDED WITH RESPECT TO THE RFA VIOLATIONS

A. Vacatur Is Appropriate to Redress the APA Violations

Where the court finds a violation of the APA, the agency's action should be reversed and set aside. That is the remedy provided in the APA. 5 U.S.C. § 706(2). Remand without vacatur should be entered only in the rare circumstance where the court finds the challenged agency action invalid, but not seriously deficient or when vacatur would have disruptive consequences or fails to serve the interests of the prevailing party that was harmed by the agency's error. *See, e.g., Envtl. Def. Fund v. EPA*, 898 F.2d 183, 190 (D.C. Cir. 1990) (where no party asked that the challenged rules be vacated and doing so temporarily would defeat the petitioner's purpose). That is not the case here.

B. A Permanent Injunction Should Be Entered With Respect to the RFA Violations

"The basis of injunctive relief in the federal courts has always been irreparable harm and inadequacy of legal remedies." *Beacon Theaters, Inc. v. Westover*, 359 U.S. 500, 506-07 (1959). A plaintiff is entitled to a permanent injunction with respect to all claims not subject to vacatur, if it has demonstrated,

(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). Here, the record demonstrates that plaintiffs will suffer irreparable injury were the Final Rule to become effective—injury that cannot be cured by money damages. In addition, the balance of hardships tips in favor of plaintiffs here and the requested injunction serves the public interest as well.

1. The Final Rule Will Cause Irreparable Harm to Plaintiffs That Money Damages Cannot Compensate

Plaintiffs will suffer irreparable harm without an injunction. Plaintiffs will lose

customers, and thus goodwill, if the Final Rule is implemented. The uncontradicted evidence

establishes how the injury will occur and that it is irreparable. As one of the plaintiffs explained, complying with the Final Rule, if compliance is even possible, "will create massive disruption to existing seafood processing and sales, and will increase costs and impose a substantial burden on our company." See Exh. F: Decl. of Daniel C. Occhipinti, ¶ 13. NMFS admitted that "[c]ost to consumers would be manifested via higher prices due" to the Final Rule. AR 6935: Final RFA Analysis at 5. In plaintiffs' experience, past efforts to pass along the increases in prices of seafood have resulted in loss of customers. See Exh. A: Decl. of Justin Conrad at ¶¶ 4-6. What is past is prologue in this instance. Whether they attempt to pass costs to consumers or try to bear the cost, the Final Rule will have an immediate and detrimental impact on plaintiffs that will result in the loss of customers and good will and will cause immediate and significant disruption to plaintiffs' businesses. See Exh. B: Decl. of Sean O'Scannlain at ¶ 7, 8; Exh. C: Decl. of Santiago Alvarez at ¶¶ 11, 12; Exh. A: Decl. of Todd Conway at ¶ 24; Exh. D: Decl. of Justin Conrad at ¶ 10; Exh. F: Decl. of Daniel C. Occhipinti at ¶ 13; Exh. E: Decl. of John Connelly at ¶ 17. Monetary damages cannot cure this harm because they are not available from the government. For an injury to be "irreparable," legal remedies after the fact must be inadequate to restore the party seeking a stay to the status quo ante. Baker v. Socialist People's Libyan Arab Jamahirya, 810 F. Supp. 2d 90, 97 (D.D.C. 2011). That is the case here.

2. The Balance of Hardships and Public Interest Favor a Permanent Injunction

The balance of hardships weighs in favor of permanent injunctive relief for a variety of reasons. First, an injunction would stop the government from exercising or attempting to exercise lawmaking power that it does not have. That promotes the public interest. *See Bayou Lawn & Landscape Servs.*, 713 F.3d at 1085 ("On appeal, DOL argues that it is harmed by having 'its entire regulatory program called into question.' This is not an appealing argument. If the 'entire regulatory program' is *ultra vires*, then it should be called into question."). It is in the public interest that regulations are issued only by an agency and a person within the agency authorized by Congress to do so. *See In re Medicare Reimbursement Litig.*, 414 F.3d 7, 12 (D.C.

Cir. 2005) ("As the district court noted, moreover, even if the delay increased HCFA's administrative burden, the additional "burden [would] not outweigh the public's substantial interest in the Secretary's following the law.").

Conversely, the government will not be harmed by being forbidden to exercise authority that Congress did not give it. It cannot dispute that it has other tools available to it to combat IUU fishing and FDA's authority to combat seafood fraud is not affected by enjoining the Final Rule. Accordingly, both the balance of harms and the public interest favors the entry of permanent injunctive relief.

CONCLUSION

For the foregoing reasons, summary judgment should be granted in favor of the plaintiffs and the Court should vacate and enjoin the Final Rule.

Respectfully submitted,

s/Robert P. Charrow Robert P. Charrow (DC 261958) Laura Metcoff Klaus (DC 294272) GREENBERG TRAURIG LLP 2101 L Street, N.W., Suite 1000 Washington, D.C. 20037 Tele: 202-533-2396; Fax: 202-261-0164 Email: charrowr@gtlaw.com; klausl@gtlaw.com

Counsel for Plaintiffs