EXECUTIVE SUMMARY

The Department of Agriculture’s Food Safety and Inspection Service (FSIS) is statutorily charged with monitoring the nation’s slaughter establishments to ensure food safety and the humane treatment of livestock.¹ In order to improve the effectiveness of this oversight, public interest organizations frequently submit requests for rulemaking to the agency under the Administrative Procedure Act.² Unfortunately, FSIS responses to these requests are often delayed and/or consist of denials.

Greenfield sought to better understand how FSIS reviews and prioritizes these petitions for rulemaking. We analyzed all 69 petitions for rulemaking submitted to FSIS since 2005,³ as posted on the agency’s website.⁴ These rule change requests covered topics such as standards and processes for food safety, import/export requirements, humane handling/slaughtering, and food labeling.

Our analysis found that agribusiness representatives mostly request action that FSIS has the discretion, but is not required, to undertake. In contrast, public interest petitioners are more likely to request protections that are required by statute, and that the petitioners argue the agency is not sufficiently providing. Our analysis also shows that:

● FSIS is less likely to respond to public interest requests than those from agribusiness,
● FSIS is more likely to deny requests for actions involving animal welfare or public health concerns, and
● FSIS almost always disagrees that public interest petitions demonstrate that animal welfare or public health is in danger.

² 5 U.S.C. § 553 (“Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.”).
³ One petition has recently been voluntarily withdrawn from consideration by the petitioner, and therefore was not included in our analysis.
⁴ 75 Fed. Reg. 3847 (Jan. 25, 2010) (stating that “effective January 25, 2010 the Agency will begin to post all petitions for rulemaking that it receives, along with any supporting documentation” on its website). Note that seven of the petitions posted to FSIS’s website predate this requirement, and the earliest posted petition was submitted on July 8, 2005. It is unclear whether these seven petitions constitute all of the petitions submitted to FSIS between July 2005 and January 2010. However, the remaining 62 petitions should be inclusive of all petitions submitted after 2010.
In over ten years, the agency has only granted three public interest requests. Two of those requests were for improved animal treatment but FSIS has only implemented one so far.

We also identified some common suboptimal practices in how petitioners are requesting rule changes and give our recommendations for writing stronger petitions.

Finally, we briefly review the legal basis for challenging delays or denials and offer some thoughts on such challenges.

FSIS PETITION REQUEST AND RESPONSE PATTERNS

Methods:

In order to determine what, if any, factors influence FSIS’s likelihood of responding to and granting requests, we categorized each petition along the following dimensions:

1. Whether the petitioner(s) represented agricultural businesses or the public interest (the latter focused primarily on consumer safety or animal welfare, but was defined broadly to include anything that was not in the interest of large agribusiness);⁵
2. Which authorizing statute the request implicated;⁶
3. Whether the authorizing statute mandated the action requested or merely authorized it;
4. Whether the request implicated animal welfare;⁷
5. Whether the request was granted⁸ or denied;
6. If the request was denied, the reason(s) provided for denial;
7. How long it took FSIS to issue a response, if any; and
8. How long it took FSIS to implement any responsive change, if any.⁹

We decided to categorize requests helpful to small independent farmers, such as requiring a definition of “grassfed beef” or restricting the claim “Product of USA,” as “public interest” petitions. Although the petitioners technically represent a kind of agribusiness, we believe these requests support alternatives to the large, politically powerful agribusiness conglomerates that usually have the ear of the agency. For this reason, and for the actual content of the requests, we believe granting these petitions is in the public interest and will ultimately also benefit consumers and animals. We also categorized entities which sought greater regulatory oversight, ostensibly to advocate on behalf of consumers, as “public interest groups,” even if their underlying motives were dubious, such as in the case of the petition submitted by “Stop Islamization of America.”

FSIS has jurisdiction to issue regulations under the Acts listed at fn 1, as well as the Agricultural Marketing Act (AMA), 7 U.S.C. § 1621 et seq.

It is common for animal protection nonprofits to submit petitions that focus on issues of labeling or food safety without addressing animal welfare directly (such as requesting that a food be banned due to health concerns). To be as conservative as possible, we coded such petitions as implicating animal welfare when the petitioners are well known to be animal protection advocates, the petition had a fact or legal argument section on welfare, or if the stated “interest of petitioners” focused on animal welfare.

We erred on interpretations most generous to FSIS; if the petitioner got most of what was asked, or was able to achieve a desired outcome following a response from FSIS, we coded that petition as “granted” even if FSIS did not grant the petition in a more technical sense.

Here again we erred towards generosity for FSIS; implementation dates were set as soon as changes were proposed or announced, whichever was earlier.

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We attempted to answer two questions: 1) whether FSIS was more likely to grant petitions requesting action *mandated* by the authorizing statute than those requesting *discretionary* action, and 2) whether FSIS was more likely to consider and grant petitions which did not concern animal welfare.

To determine whether a requested action was mandatory or discretionary, we analyzed each request using the standards for judicial review under the APA, 5 U.S.C. § 500 et seq. If the statute said with particularity that the agency “shall” do the action requested, we coded the request as mandatory. Similarly if the statute said the agency “may” or “is authorized” to do the action requested, we coded the request as discretionary. Following the precedent set by the Supreme Court in *Massachusetts v. Environmental Protection Agency*, if the relevant statutory provision implied that the agency “shall” make a determination which would then lead to the requested action, and the agency had not yet made such a determination, we coded the petition request as mandatory.

Many petitions, however, did not fall within these bright line rules. Often, the petitions implicated statutory provisions in which FSIS is clearly required to do *something*, but where that *something* is so undefined as to give the agency *de facto* discretion over its execution. Our framework in these cases derived from the Supreme Court precedent in *Citizens to Preserve Overton Park, Inc. v. Volpe*. Our rule was: if the requested action triggered a mandatory statutory provision with sufficiently particular standards and the requested action arguably met those standards, we coded that petition as mandatory. If the requested action triggered a statutory provision with a mandate, but one with vague or no standards, we coded that petition as discretionary.

Two provisions frequently implicated in the FSIS petitions illustrate our rule. First, many petitions requested that a food product be banned for human consumption on account of it being “adulterated” under the Federal Meat Inspection Act (FMIA). The relevant FMIA provision states that “the term

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10 The use of statutory language stating that the agency “shall” do a prescribed action, along with specific deadlines, is usually treated by courts as indicative of a mandatory duty. See Drury D. Stevenson, *Special Solicitude for State Standing: Massachusetts v. EPA*, 112 PENN ST. L. REV. 1, 52–53 (2008) (discussing in depth the use of “shall” to denote mandatory versus discretionary action).


12 *Id.*

13 See Cass R. Sunstein, *Reviewing Agency Inaction After Heckler v. Chaney*, 52 U. Chi. L. Rev. 653, 657-9 (1985). In *Overton Park*, the Court addressed when agency action is precluded from judicial review because it is “committed to agency discretion by law” under the APA. *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971). The Court stated that there could be judicial review if there was “law to apply” in assessing the decisions of the agency. A court can review whether an agency’s action (or inaction) is contrary to the applicable statute if the statutory provision, measured against the particular claim of the petitioner, gives “judicially administrable standards by which to assess the claim.” With such standards, the court has some measure by which to assess agency decisions. If there are no such standards, the court has no basis for determining if the agency acted contrary to law, and the action is within the agency’s discretion to undertake (or not).

14 Doing so, of course, collapses the test for judicial review (can a court review the agency action or inaction?) with a decision on the merits (did the agency, in fact, violate their mandate or act within their discretion?). However, Sunstein himself is well aware of this seeming collapse, and is not concerned. For our purposes, this framework allows both for an estimation of whether these decisions by FSIS could be reviewed by a court and a sense of the likelihood that the plaintiffs will prevail on the merits.
adulterated’ shall apply” to any meat product under a series of conditions. The statute then outlines twelve conditions which make a meat product “adulterated,” including “if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome,” or “if it bears or contains any poisonous or deleterious substance which may render it injurious to health.” In most cases, the petitions outlining claims of adulteration offered copious facts that one of these conditions had been met. It seemed clear to us in this case that there are “judicially administrable standards by which to assess the claim” of adulteration, or at a minimum, a requirement that the agency make a determination of healthfulness of the claimed substance. We therefore coded these petition requests as mandatory.

The other common request was to ban product claims that the petitioner(s) felt are misleading or false. The FMIA states that “[t]he term ‘misbranded’ shall apply to any ... meat or meat food product ... if its labeling is false or misleading in any particular.” However, the statute provides no further clarification on how to determine whether a label is false or misleading. In these cases, it is difficult to see what the “judicially administrable standards” might be to determine whether, in fact, any given product claim is misleading or false. As such, we coded these petition requests as discretionary.

Requests regarding humane handling or slaughtering also illustrate the rule quite nicely. The Humane Methods of Slaughter Act (HMSA) gives two very specific definitions of what is considered humane for “slaughtering and handling”:

(a) in the case of cattle, calves, horses, mules, sheep, swine, and other livestock, all animals are rendered insensible to pain by a single blow or gunshot or an electrical, chemical or other means that is rapid and effective, before being shackled, hoisted, thrown, cast, or cut; or

(b) by slaughtering in accordance with the ritual requirements of the Jewish faith or any other religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument and handling in connection with such slaughtering.

However, these specifics really only apply to humane slaughter. The provision is essentially silent on what the standards should be on humane handling, although humane handling is mandated. As such, we coded all petitions that requested certain regulations on humane handling (as opposed to slaughter

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19 FSIS has issued several regulations on what they consider to be humane handling, which include the availability of food and water, ramps and pens in good repair, and handling that causes minimal excitement in the animals. 9 C.F.R. § 313.
specifically as outlined by this provision) as discretionary, notwithstanding the mandatory appearance of
the provision.

Finally, we coded FSIS’s reasons for denial into five categories:

1. FSIS denied jurisdiction over the requested action,
2. FSIS disagreed with the legal reasoning of the petitioner,
3. FSIS disagreed with the facts provided by the petitioner,
4. FSIS claimed the petition provided insufficient evidence to support the requested action, and/or
5. FSIS claimed the issue was not a priority.

The “insufficient evidence” category applied when FSIS stated that they were open to the possibility of
the requested action but felt more data was needed to definitively choose a course of action, while the
“disagreement with the facts” rationale applied when FSIS affirmatively disagreed with the supporting
facts and conclusions alleged in a petition, and consequently denied that the petition pointed to a
problem that needed to be remedied.

Results:

Requests

Of the 69 total petitions reviewed, 12 petitions requested mandatory agency action, while the
remaining 57 petitions contained discretionary requests. While the overall number of petitions
submitted by agribusiness representatives and public interest groups was similar (36 and 33,
respectively), their rates of mandatory versus discretionary requests differed significantly.

With the exception of one petition, all industry stakeholder petitions requested only discretionary
actions, whereas a third of public interest groups’ petitions concerned a mandatory duty. This gap
suggests differing levels of baseline satisfaction with FSIS’s administration of its statutory duties —
agribusiness representatives likely view FSIS as generally compliant with statutory mandate, while public
interest groups see failures on the agency’s part to independently execute its mandatory duties. This
appears to be especially true with regard to animal welfare. Of the 36 petitions submitted by
agribusiness representatives, none implicated animal welfare. However, 19 public interest petitions
concerned animal welfare, with 4 of those petitions implicating a mandatory duty, and the remaining 15
requesting a discretionary agency action.

Responses

Currently, just over half of the petitions (37) have received final responses, with mandatory petitions
receiving final responses at a significantly higher rate — 75%, compared with 49% for discretionary

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20 We have reviewed the 69 non-withdrawn petitions on the FSIS website submitted before July 1, 2019. All of the
21 Of these discretionary petitions, 8 fell into the Overton Park, “no law to apply” category.
 petitions. Because the overall number of mandatory petitions submitted was low, and one mandatory petition was submitted so recently that it would not yet be expected to have received a final response, the 75% response rate is likely an underestimate of FSIS’s response rate for mandatory petitions.

Although agribusiness representatives and public interest groups received final responses at a similar rate, in at least six cases, FSIS made final determinations on petitions submitted by public interest groups only after being sued for its failure to respond. In the absence of such legal intervention, FSIS’s response rate was 50% for agribusiness representatives, and 39% for public interest groups. For those discretionary petitions where there was no legal intervention, the response rate was 51% for agribusiness representatives (18 petitions), and 27% for public interest petitioners (6 petitions).

Petitions which implicated animal welfare appeared to receive final responses from FSIS at a higher rate than non-welfare petitions (63% response rate for welfare petitions, versus 50% for non-welfare petitions), but those responses were considerably more likely to be unfavorable than for non-welfare petitions (53% versus 22% denial rate).

Response times

The amount of time it took FSIS to issue a final response tended to favor agribusiness representatives. Overall, it took FSIS an average of 304 days longer to respond to petitions submitted by public interest groups (1163 days versus 859 days). If further considering time to implementation of a granted petition request, the spread grows even further, to 899 days longer for public interest groups.

Grant rates

Petitions submitted by agribusiness representatives were significantly more likely to garner a final response from the agency, to receive a favorable determination, and to have the requested action implemented, than those submitted by public interest petitioners. Agribusiness representatives received

\[22\] 50% (18 petitions) and 58% (19 petitions), respectively. However, the response rates for discretionary non-welfare petitions is also worth noting: agribusiness representatives received responses 51% of the time, whereas public interest petitioners received responses only 29% of the time.

\[23\] Of course, we have no knowledge of whether industry groups ever threaten legal action when FSIS is tardy with responses, but we have no reason to believe that this is common.

\[24\] Currently, FSIS’s rate of response to mandatory petitions submitted by industry groups is 0%, but we consider this an unreliable figure because only one such petition was submitted, and it was submitted recently, before FSIS would be expected to provide a final response.

\[25\] The mean response times were 859 days for agribusiness representatives and 1163 days for public interest groups. The spread is even more significant if looking at median, rather than mean, response times, which were 735 days for agribusiness representatives, and 1163 days for public interest groups.

\[26\] Based on our data, the average days to implementation of granted petition requests was 683 days for industry petition and 1583 days for public interest petitions. The average days to implementation for industry petitions is shorter than the average days to final response because in some cases, the underlying request of a petition was effectuated prior to FSIS’s issuance of a final response letter. The shortest response time, 28 days, was in connection with an industry stakeholder petition, and the longest response time, 2398 days, was in connection with a public interest group petition.
favorable decisions for 13 petitions, versus only 3 petitions for public interest groups in over 10 years. Additionally, while FSIS went on to execute the regulatory action requested in each industry stakeholder petition it granted, it did not do so consistently for public interest groups. While all 13 granted petitions from agribusiness representatives were implemented, only 2 of the 3 granted public interest petitions have been implemented to date. The sole petition that was granted but not implemented was one relating to animal welfare at slaughter.

It should be noted that because only public interest groups submitted welfare petitions, FSIS’s lower grant rates for these petitions could, in part, reflect agency bias against this group of petitioners, rather than agency disinclination to grant welfare petitions. In fact, the discrepant grant rates for non-welfare petitions submitted by public interest groups versus those submitted by agribusiness representatives suggest that petitioner affiliation is almost certainly a confounding factor. 37% of discretionary non-welfare petitions (13 petitions) submitted by agribusiness representatives were granted and implemented, while none of the 7 were granted for public interest groups.

**Denial rates**

Overall denial rates were significantly higher for public interest groups, at 48%, compared with 14% for agribusiness representatives. Denial rates were particularly lopsided for petitions dealing with specific subject areas. For example, for those petitions dealing with slaughter or handling regulations, agribusiness representatives received responses in 50% of cases and public interest petitioners received responses 60% of the time, but agribusiness representatives received no denials, while public interest groups had 4 of the 6 requests for which they received final responses denied. For petitions dealing with labeling issues, agribusiness representatives received responses in 52% of cases, while public interest groups received responses in 42% of cases. Ultimately, 19% of the agribusiness representatives’ labeling petitions were denied, versus 42% of the public interest group petitions.

Denial rates also varied considerably between welfare and non-welfare petitions, with welfare petitions being denied at more than double the rate of non-welfare petitions (53% vs. 22%). Of the 21 total denials, 9 were “without prejudice,” meaning that petitioners can seek reconsideration upon putting forward additional information to support their original requests. Non-welfare petitions were almost three times as likely to receive “without prejudice” denials (7 of 11 denials vs. 2 of 10 denials for welfare petitions).

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27 Unlike some other agencies, FSIS has not issued any guidance about when it will issue a straightforward denial, versus one “without prejudice,” so it is unclear how they determine when to deny a petition with or without prejudice, or how consistently they apply these standards.

28 Further, the agency affirmatively requested follow-up information in 27% of the non-welfare petition denials, compared with only 10% of welfare petition denials.
Submitted | Responses | Granted | Implemented
---|---|---|---
Agribusiness | 36 | 18 | 13 | 13
Public Interest | 33 | 19 | 3 | 2

**Reasons for denial**

In response to agribusiness petitions, FSIS claimed three basic rationales for denial: lack of authority to take the requested action, disagreement with the facts stated in the petition, or having insufficient evidence to support the need for or suitability of the requested action. FSIS used these same denial reasons for public interest group petitions, and additionally denied these petitions on account of disagreement with the stated legal framework (for 4 public interest petitions, of which 3 related to animal welfare), and due to the low agency priority of the requested action (for one public interest, pro-welfare petition). For agribusiness representatives, FSIS disagreed with the provided data contained in just one petition, while it disagreed with data provided in 13 public interest group petitions. Additionally, although FSIS cited “insufficient evidence” as a reason for denial for one-third of all petitions, it did so only for non-welfare petitions.

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<th>No Authority</th>
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<th>Insufficient Evidence</th>
<th>Disagreement w/ Law</th>
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<td>2</td>
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When FSIS denied public interest group petitions on the basis of disagreement of fact, the agency tended to note its disagreement with the scientific facts and conclusions set forth in a petition (e.g., that “hepatic lipidosis,” or fatty liver, in ducks or geese signals the presence of disease), and to offer a countervailing interpretations (e.g., that although a fatty liver “might be considered abnormal ... the

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29 The one case in which FSIS disagreed with the facts stated in an industry stakeholder petition was concerning Tyson Foods’ assertion that certain “Process Verified Program” (PVP) label claims approved by FSIS for use by Perdue, such as “humanely raised” and “raised cage free,” were misleading to consumers. Although FSIS concluded that Perdue’s PVP claims were “truthful and not misleading” and thus denied Tyson’s petition, it did so not because it disagreed with Tyson’s consumer data showing that consumers misinterpreted the Perdue PVP labels, or that terms like “humanely raised” are subjective and convey different things to different consumers. Instead, FSIS determined that notwithstanding potential consumer confusion about these labeling claims, the PVP labels were not misleading because the program was explicitly designed to convey only that USDA verified a company’s adherence to its self-defined process controls for a particular claim, rather than that the company met USDA standards or that the underlying claim is objectively true. Further, the agency effectively invited Tyson to alternatively resolve its grievance by applying for its own PVP claims, stating, “USDA’s Process Verified Program is a voluntary, user-fee program that is open to all companies. Companies that invest the resources to participate in the USDA PVP typically do so to gain a marketing advantage for their products. Perdue’s competitors are free to participate in the program and obtain the same marketing advantage.”
fatty changes are exactly those that would be expected due” from overfeeding ducks or geese, and thus is the result of a “physiologic condition” rather than disease). In addition to disagreeing with information provided by public interest group petitioners more frequently, FSIS also appeared to generally be more skeptical of the evidence public interest group petitioners must submit before it would be persuaded. The agency frequently challenged petitioners’ ability to draw the proffered conclusions based on the scientific evidence submitted or the appropriateness of extrapolating from experimental findings in its responses to public interest groups, but not for agribusiness representatives. In one example, FSIS acknowledged that six published studies supported the petitioner’s argument, but nevertheless concluded that “these studies are limited in their ability to conclusively determine” the point the petitioner sought to make because the studies had not flawlessly ruled out all possible variables.

Perhaps due to a higher evidentiary bar for public interest groups, its rate of denials based on a disagreement of fact was substantially higher than for agribusiness representatives, at 81% versus 20%, while its rate of denials based on “insufficient evidence” was significantly lower, at 19% versus 60%. Essentially, when FSIS was not convinced by the evidence submitted in a petition, it effectively told public interest groups, “your evidence has not overcome all doubt, so we disagree with you,” while it told agribusiness representatives, “your evidence has not convinced us yet.”

The discrepant rate of denials for “insufficient evidence” is significant because petitions denied on this basis were always dismissed “without prejudice,” and denials without prejudice allowed petitioners to put forward additional information to support their original requests. In every case where an industry stakeholder petition was denied without prejudice, FSIS not only advised the petitioner of their ability to submit additional supporting evidence, but even provided specific guidance about what type of information petitioners should include in any such resubmission. In one case, FSIS stated that a revised petition “might include data on consumer expectations about the composition of corned beef, as well as organoleptic data to show that the quality of the products would not be affected by the inclusion of

31 See, e.g., Letter from USDA’s Food Safety Inspection Service to the Center for Science in the Public Interest (July 31, 2014),https://www.fsis.usda.gov/wps/wcm/connect/73037007-59d6-4b47-87b7-2748edaa1d3e/FSIS-response-CSPI-073114.pdf?MOD=AJPERES (“[A]lthough some published articles suggest an association of increased severity of illness with [antibiotic resistant] Salmonella, these studies are limited in their ability to conclusively determine whether the [antibiotic resistance] in itself caused the increased severity.”).
32 See Letter from USDA’s Food Safety Inspection Service to the Humane Society of the United States, supra note 30 (“[T]he findings in the study are based on the administration of amyloid to genetically susceptible mice under experimental conditions... [and] does not ... establish a link between the presence of amyloid in foie gras and the development of human disease.”).
33 See Letter from USDA’s Food Safety Inspection Service to the Center for Science in the Public Interest, supra note 31.
34 Interestingly, every time FSIS denied a public interest group’s petition based on insufficient evidence, the agency also cited its disagreement with the facts alleged in the petition as a reason for denial. However, it never cited both denial reasons together for agribusiness representatives.
additional beef heart meat or the inclusion of tongue meat or esophagus,” and in another, included an attachment outlining specific technical issues to address in a subsequent petition.

FSIS provided no such guidance for any of the public interest groups who had their petitions denied for insufficient evidence. Instead, these petitioners generally received a near-identical statement stating, “For the reasons discussed above, FSIS is denying your petition. Because our denial is without prejudice, you are not precluded from submitting a revised petition that contains additional information to support the requested action.” In one case, FSIS did not even advise petitioners of their ability to resubmit a revised petition, although the denial was technically “without prejudice.” It failed to do so even though FSIS appeared to put considerably more effort into these denial letters for public interest group petitioners — the denial letters where “insufficient evidence” was provided as a reason for denial was on average 8.6 pages in length for public interest groups, compared with just 2 pages in length for agribusiness representatives.

Conclusion:

Our analysis has demonstrated that FSIS is less likely to respond (without threat of legal action) to requests from public interest groups than agribusiness representatives, is more likely to decline requests for strengthened regulations impacting animal welfare or public health than industry concerns, and almost always bases public interest petition denials on a disagreement that the evidence presented suggests animal welfare or public health is in danger. In over ten years (and possibly much longer), the agency has only granted three public interest requests at all. Two of those requests were for improved animal treatment but FSIS has only implemented one of those requests.

37 See, e.g., Letter from USDA’s Food Safety Inspection Service to SIOA, a Division of the American Freedom Defense Initiative (Sept. 9, 2016), https://www.fsis.usda.gov/wps/wcm/connect/dcda4cb4-2612-4283-a9a7-0f97d976e022/12-02-FSIS-Final-Response-090916.pdf?MOD=AJPERES.
38 Letter from USDA’s Food Safety Inspection Service to the Center for Science in the Public Interest (Feb. 7, 2018), https://www.fsis.usda.gov/wps/wcm/connect/b3f61f6e-47e5-4164-ac60-913c1ff66b26/FSIS-response-CSPI-020718.pdf?MOD=AJPERES (“For the reasons discussed above, FSIS is denying your October 1, 2014, petition without prejudice.”).
39 We surmise that this both due to the fact that FSIS usually cites multiple reasons for public interest petition denials and that the agency anticipates future litigation over these denials, but not for agribusiness responses.
CURRENT STATE OF PETITION REQUESTS IN FRONT OF FSIS

As of October 1, 2019, there are 14 public interest petitions that have yet to receive a response from FSIS, with submission dates as far back as 2010. The outstanding public interest petitions generally fall into three categories: labeling issues, slaughter and handling issues, or import standards.\(^\text{40}\) Seven seek new or amended labeling regulations—for example to prohibit “Product of USA” labeling for products that are not wholly produced in the U.S., to revise requirements for safe handling instructions required to be on meat labels, and to restrict the use of “natural” claims. Two pro-welfare petitions fall into this category. One, submitted in 2013, seeks a new rule requiring disclosure of antibiotic use in meat and poultry products, as well as clarification of the existing “antibiotic free” labeling claim. The other seeks mandatory production-method labeling on shell eggs, over which FSIS does not have jurisdiction, and supplants a similar, earlier petition which was denied by FSIS, so it appears unlikely to receive a response.

Four of the outstanding petitions relate to slaughter or handling requirements, including a request for more serious enforcement actions for HMSA violations, more transparency regarding plant suspension records, and regulations to address bird handling and slaughtering practices that result in adulteration.

Two petitions relate to mandatory FMIA food safety provisions governing import standards. Although these petitions, submitted in 2014 and 2017, have yet to receive a response, we suspect that FSIS will eventually issue decisions regarding these petitions. It has responded to all other similar petitions relating to mandatory import standards, without the petitioners having to initiate an unreasonable delay suit, even though in one instance, FSIS took over 6.5 years to respond.

COMMON SUBOPTIMAL PRACTICES BY PETITIONERS AND RECOMMENDATIONS

Our analysis shows that FSIS is likely to deny petitions requesting improvements for animal welfare on the basis of a disagreement of fact. As such, petitioners should be prepared to present as much scientific evidence as possible to maximize their chance of success, either at the agency level, or in a legal challenge to the denial. Ideally, scientific studies with notable deficiencies, such as small sample size or inability to control for a certain variable, should be supplemented by other studies which mitigate those specific concerns. Framing the request as required under a mandatory provision is also ideal, as FSIS is significantly more likely to respond to such requests, and a denial under a mandatory provision creates a more colorable legal challenge.

Although petition grants or denials seem to be primarily driven by the nature of the request and not by the quality of the petition, a poorly written petition may contribute to a delayed or denied response. Additionally, for petitioners looking to challenge denials in court or share the petition with media, a clear and compelling narrative is crucial.

\(^{40}\) One of the 14 petitions does not fall into these categories. It seeks mandatory occupational safety and health standards regulating work speeds on production lines in the meatpacking and poultry industries to ensure worker safety. Because FSIS historically has denied authority to regulate around worker safety, we exclude this petition from this analysis.
Below are several common drafting errors we found that undermined the otherwise strong evidence and arguments put forth in the reviewed petitions. We offer our suggestions for drafting more effective requests.

Problem 1: Petitioners burying the lede.

Many petitions are written like academic articles or legal briefs. Unfortunately, there are often pages to get through before the reader finds the actual request for the agency. Petitioners often go to great lengths to review the policy implications of their requested action before clearly outlining what the requested action actually is. As such, it is often hard to distinguish whether the petitioner is describing an existing problem, the proposed solution, or trying to preempt possible counterarguments. Legally trained petitioners cite case law in their introductions and have paragraphs describing the “interests of petitioners” in anticipation of litigation years down the road, all before the reader has a clear sense of what is being asked.

Solution: Begin with a clear and concise opening summary.

We recommend starting with a cover page or an opening summary, delineating clearly (but briefly) the problem, the relevant statutory and regulatory provisions, and the basic request. Any extensive evidence and policy arguments are easier to follow when the reader already has a basic understanding of what the petition is seeking and why.

Problem 2: Petitions are missing a statutory framework.

A shocking number of petitions never cite the relevant statute under which the agency’s duty falls. As a result, it is nearly impossible to tell whether the agency is required to do what is requested and when (if ever). Given that many of the petitions (especially from the public interest community) are written with potential litigation in mind, and a court always reviews agency action or inaction from the framework of Congressional authority delegated under the relevant statute, this omission is quite surprising.

Solution: Include the correct statutory provision and outline the agency’s mandatory and/or discretionary duties by law.

To aid the reader in understanding not only what the petition is seeking, but also whether the agency is required to act in response to the request or facts presented, always be sure to cite the relevant statutory provision. This is especially true if, as the petitioner, you think you might need to sue the agency in the event of no response or a denial. A petition is much stronger if it clearly lays out for the agency what it is expected to do in response to the request. We also encourage drafters to include a short statement to this effect in their concise opening statement.
**Problem 3: Reader is overwhelmed with multi-page factual or legal arguments.**

Many public interest petitioners know that it is an uphill battle to get a request granted by USDA. They also usually expect to sue for undue delay if the agency ignores their request for years. As a result, many of these petitioners (for good reason) fill their request with pages of scientific evidence, policy arguments, surveys, and legal analysis. Unfortunately, if not organized thoughtfully, these can overwhelm the reader to the point where the basic problem and the (possibly simple) solution gets lost.

**Solution: Consider including material for legal challenge in an appendix.**

Much like our first suggestion, consider moving all the relevant material for a legal challenge to an appendix, such as petitioners’ interests (for challenges about standing), scientific evidence (studies and surveys), and legal arguments in anticipation of court briefs. This way, it is still included in the petition but the stronger narrative and concise statutory framework are not lost in the details.

**CHALLENGING PETITION DELAYS AND DENIALS**

Advocates often seek judicial review after an agency has ignored or denied their petition for rulemaking. In the case of no response at all, a court can determine that agency action was unreasonably delayed under the APA, and it can compel the agency to make a determination on the request at issue. In *Telecommunications Research & Action Ctr. v. F.C.C.*, the D.C. Circuit articulated several factors for evaluating claims of agency delay, including whether the amount of time taken by an agency to make a decision is governed by a “rule of reason,” whether human health and welfare are at stake, whether expediting the requested action affects agency activities of a higher priority, and the “nature and extent of the interests prejudiced by delay.”

The Supreme Court has made clear that substantive review of petition denials is also available; however, such review is ‘extremely limited’ and ‘highly deferential.’ The reviewing court will apply the APA’s arbitrary and capricious standard of review in these cases. The arbitrary and capricious standard allows

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41 750 F.2d 70, 80 (D.C. Cir. 1984).
42 Massachusetts v. EPA, 549 U.S. 497, 527-8. In particular, courts defer to agencies when deciding which actions to take “in light of limited resources and ongoing budget uncertainties.” WildEarth Guardians v. U.S. E.P.A. (D.C. Cir. 2014) 751 F.3d 649, 651. However, by relying on the discretion inherent in priority setting, agencies cannot completely “abandon[] the implementation and enforcement of regulatory programs,” thereby essentially replacing Congressional policy decisions with their own. Cass R. Sunstein & Adrian Vermeule, *The Law of "Not Now": When Agencies Defer Decisions*, 103 Geo. L.J. 157, 176 (2014). Judicial review in such cases is warranted to protect agencies from undue influence and to vindicate the will of Congress. Cases such as *Massachusetts v. EPA* and *American Horse v. Lyng* suggest that courts might be willing to review agency inaction if there is a suspicion that agencies are refusing to regulate for illegitimate reasons (such as undue industry or political influence). See Massachusetts v. EPA, 549 U.S. 497 (2007); see also American Horse Protection Ass’n, Inc. v. Lyng, 812 F.2d 1 (D.C. Cir. 1987). For more on this, please see our forthcoming chapter, “Is Never Good For You? The Law of Regulatory Avoidance and Challenging the Abdication of Federal Farm Animal Welfare Protection” in *What Can Animal Law Learn from Environmental Law*, 2nd Edition, for an in-depth discussion of the challenges and potential for judicial review of regulatory circumvention by FSIS.
43 *De novo* review is reserved for adjudicatory actions or in proceedings to enforce agency action.
the court to consider “if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”

Although this review is a “searching and careful one,” it is also a narrow one—the court cannot “substitute its judgment for that of the agency.” However narrow this review, the court must ensure that the agency has “articulated a satisfactory explanation for its action, including a rational connection between the facts found and the choice made,” and that the agency’s decision “reflect[s] reasoned decision making based on evidence in the record.” In conducting this analysis, a court may not “second guess” an agency’s conclusions regarding the reliability of petitioner’s data, or fail to respect agency expertise by accepting the scientific judgments of non-agency experts over those of the agency without cause. Thus, if any “rational basis” exists, a court “must affirm the agency’s decision ... even if the court disagrees.” However, on the other hand, a court may not make up for “deficiencies” in agency decisions by “supply[ing] a reasoned basis for the agency’s action that the agency itself has not given.”

Since the majority of public interest and animal welfare petitions are denied by FSIS on account of factual disagreements and scientific evidence, we briefly review the legal doctrine for challenging these types of denials.

It is very difficult to challenge the denial of a petition on the basis of an agency’s rejection of scientific data proffered by petitioners, because a court is unlikely to question the credibility of the agency’s scientific conclusions in favor of competing conclusions presented by advocates except in extraordinary cases. However, while a court will generally not allow advocates to supplant their science for that of an agency, it may vacate and remand agency decisions in limited cases where the agency’s apparent reasons for making a determination are not clear or are unreliable.

46 Henley v. Food & Drug Admin., 77 F.3d 616, 620 (2d Cir. 1996) (internal quotations omitted).
48 Compassion Over Killing v. U.S. Food & Drug Admin., 849 F.3d 849, 856 (9th Cir. 2017) (“While Plaintiffs dispute the FDA’s decision to reject their scientific evidence, the Court will not second guess the FDA’s conclusion that these studies were insufficiently reliable, largely because they failed to control for relevant variables.”).
49 Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep’t of Agric., 415 F.3d 1078, 1093–94 (9th Cir. 2005), as amended (Aug. 17, 2005) (overturning the lower court’s decision because it had repeatedly substituted its judgment for the agency’s, disagreeing with USDA’s determinations even though they had a sound basis in the administrative record, and accepting the scientific judgments of R–CALF’s experts over those of the agency.”).
51 Islander E. Pipeline Co., LLC v. Connecticut Dep’t of Envtl. Prot., 482 F.3d 79, 102-03 (2d Cir. 2006).
52 Courts require that the “grounds upon which the administrative agency acted be clearly disclosed and adequately sustained.” Sec. & Exch. Comm’n v. Chenery Corp., 318 U.S. 80, 94 (1943). This is necessary to allow courts to determine whether there is a “rational basis” for the agency action that meets the relevant governing standards. See U. S. Lines, Inc. v. Fed. Mar. Comm’n, 584 F.2d 519, 533 (D.C. Cir. 1978) (“[W]e simply cannot determine whether the final agency decision reflects the rational outcome of the agency’s consideration of all relevant factors when we have no idea what factors or data were in fact considered by the agency.”). In one
Courts may also vacate agency decisions when the administrative record on which it is based obviously contradicts the decision.\textsuperscript{53} For example, in one case, a state Department of Environmental Protection declined to approve the installation of a pipeline, citing environmental concerns, including that installation would make the pipeline route “unsuitable for shellfish and other bottom-dwelling organisms.”\textsuperscript{54} However, the evidence in the record reflected that “the pipeline installation would have benefited shellfish habitats,” leading the court to conclude that the agency’s decision was arbitrary and capricious because it “fail[ed] to acknowledge [the] record evidence directly contradicting its conclusion.”\textsuperscript{55} Similarly, the court vacated a recent decision by the Secretary of Commerce to add a citizenship question to the census questionnaire because the Secretary stated that his rationale for adding such a question was to obtain the “most complete and accurate” data possible, when the record was clear that adding the question would result in less accurate data.\textsuperscript{56} Even if an agency’s decision does not directly contradict the record evidence, the decision may still be set aside if there is evidence that the agency ignored relevant evidence,\textsuperscript{57} or if it “cherry-picked” evidence to such an extent that there is “significant doubt about the ultimate conclusion reached.”\textsuperscript{58}

Perhaps the clearest way to rebut the presumption of regularity ascribed to agency decision-making is to make a showing of bad faith on the part of the agency.\textsuperscript{59} Factors that evidence bad faith include improper political influence on the decision-making process, an agency’s sudden divergence from its usual decision-making protocol, an agency’s predetermination of its decision before completion of its factual evaluation, or an agency decision which is at odds with official recommendations.\textsuperscript{60} Bad faith can also be demonstrated where an agency decision is “not supported by the reasons adduce[d]” by the agency, or where the rationale provided for a decision is pretextual.\textsuperscript{61} Agency decisions which result from such bad faith agency actions “generally constitute[] arbitrary and capricious action” because they

\textsuperscript{53} See, e.g., City of Kansas City, Mo. v. Dep’t of Hous. & Urban Dev., 923 F.2d 188, 194 (D.C. Cir. 1991) (“Agency action based on a factual premise that is flatly contradicted by the agency’s own record does not constitute reasoned administrative decision-making, and cannot survive review under the arbitrary and capricious standard.”).

\textsuperscript{54} Islander E. Pipeline Co., LLC v. Connecticut Dep’t of Env’t Prot., 482 F.3d 79, 102-03 (2d Cir. 2006).

\textsuperscript{55} Id.

\textsuperscript{56} State v. Ross, 358 F. Supp. 3d 965, 1042 (N.D. Cal. 2019).

\textsuperscript{57} Consumers Union of U.S., Inc. v. Consumer Prod. Safety Comm’n, 491 F.2d 810, 812 (2d Cir. 1974) (“It must not ignore evidence placed before it by interested parties.”).


\textsuperscript{59} See, e.g., Nat’l Nutritional Foods Ass’n v. Food & Drug Admin., U. S. Dep’t of Health, Ed. & Welfare, 491 F.2d 1141, 1145 (2d Cir. 1974) (explaining that agencies are entitled to a “presumption of regularity” regarding administrative action, and that evidence of bad faith may rebut this presumption).


deprive individuals requesting agency action of “fair and honest consideration of [their] proposal,”\textsuperscript{62} and violate the principle that “the grounds upon which the ... agency acted be clearly disclosed.”\textsuperscript{63}

In one particularly stunning case involving agency bad faith with respect to an evidence-based request, Tummino v. Torti,\textsuperscript{64} FDA did virtually all of the above. Bowing to political pressure, FDA declined to approve Plan B over-the-counter without age restrictions, despite evidence showing that it was safe and effective for women of all ages, and despite the official recommendation of FDA scientists that it should be available without age restrictions. Further, plaintiffs put forward evidence that the agency pretextually claimed that it could not approve Plan B without age restrictions “because of a lack of adequate data to support appropriate use of Plan B by adolescents under 16.” An agency official later revealed that claiming there was insufficient evidence to support approval for women under age 18 was “the only way ... to appease the administration’s constituents.”\textsuperscript{65} One FDA medical officer who reviewed the available evidence retorted that “[i]f this is not enough data upon which to base a decision, it is unclear what would constitute enough data or even if that is an obtainable goal.”\textsuperscript{66} Although advocates are unlikely to encounter a case this egregious concerning the denial of an animal welfare petition, this case does suggest that under certain circumstances, it is possible to call into question an agency’s contention that a petitioner has proffered “insufficient evidence” to warrant the requested agency action.

Notwithstanding the above, a few other cases suggest that agency decision-making may sometimes be reviewable even without the agency wholly failing to state a reason for the agency’s decision, ignoring or contracting the record evidence to come to its conclusion, or engaging in bad faith conduct. For example, in one case, the court suggested that an agency decision may be “arbitrary and capricious” if it constitutes a “plainly inferior” course of action.\textsuperscript{67} In another, a different court effectively applied the less deferential “substantial evidence” test to determine whether an agency decision was arbitrary or capricious.\textsuperscript{68}

As a whole, in most circumstances, it is unlikely that petitioners can successfully challenge the denial of a petition based on an agency’s insufficient consideration of their proffered scientific evidence absent a showing of some sort of clear impropriety in the agency’s decision-making process. Accordingly, public interest groups interested in challenging petition denials for which an agency may have inappropriately ignored or contradicted the available evidence should evaluate the following to determine the likelihood of obtaining judicial review:

\textsuperscript{62} Latecoere Int’l, Inc. v. U.S. Dep’t of Navy, 19 F.3d 1342, 1356 (11th Cir. 1994).
\textsuperscript{64} 603 F. Supp. 2d at 522.
\textsuperscript{65} Id. at 530.
\textsuperscript{66} Id. at 531.
\textsuperscript{67} Pub. Citizen, Inc. v. Mineta, 340 F.3d 39, 56 (2d Cir. 2003) (“Absent any ‘satisfactory explanation’ in the rulemaking record, the adoption of a standard that permits installation of plainly inferior systems seems to us to be arbitrary and capricious.”).
1. Whether an agency has given an adequate reason for its denial. This is a foundational requirement because without such disclosure, it is impossible for a court to determine whether there was a “rational basis” for the agency’s decision. In addition to providing the reason for denial, the agency should “clearly indicate that it has considered the potential problem identified in the petition.”

2. Whether the agency failed to consider an important aspect of the problem, made a decision which clearly contradicts the record evidence, cherry-picked evidence to such an extent that there is significant doubt about the agency’s ultimate conclusion, or opted for a “plainly inferior” course of action. All of these factors suggest that an agency fundamentally does not have a “rational basis” for its decision, and will allow a reviewing court to vacate and remand the decision.

3. Whether the agency’s claim of “insufficient evidence” is credible. If an agency is claiming that it must deny a petition because petitioners have proffered “insufficient evidence” of the need or advisability of a requested action, petitioners should consider if the agency is requiring a showing of scientific evidence that defies normal scientific convention, or effectively is impossible to satisfy.

4. Whether there is any evidence that an agency may have acted in bad faith. Evidence that an agency acted in bad faith in its decision-making process can take many forms—agency officials failing to disclose the true reason for an agency decision, an agency diverging from its usual decision-making process or going against internal recommendations, or engaging in improper communications. The best evidence of such conduct would likely arise in the course of discovery (see Tummino v. Torti), but may also be available from public comments of disgruntled agency personnel, whistleblowers, or similar avenues. In addition, groups could consider requesting information regarding an agency’s particular decision-making process via the Freedom of Information Act (FOIA) to obtain more relevant information where bad faith conduct is suspected. While FOIA results may be helpful, requesters should anticipate that much of the probative information will be withheld pursuant to FOIA’s (b)(5) exemption, which protects government information which is “predecisional” or “deliberative.”

Please note that the research and analysis provided in this memorandum is provided for informational purposes only, and does not constitute legal advice or establish an attorney-client relationship.