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CITIZEN PETITION

Submitted under 21 CFR 10.30

Date: October 16, 2026

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
Submitted electronically at www.regulations.gov

Re: Citizen Petition to Establish That the Identity of a Firm Implicated in a Foodborne Illness Outbreak Is Not Confidential Commercial Information, and to Disclose Implicated Growers, Processors and Distributors Whether or Not a Recall Occurs

The undersigned submits this petition under sections 705(b) and 701(a) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.30, and requests that the Commissioner of Food and Drugs issue a regulation, and adopt the interim practices described below, governing the public disclosure of the identity of firms implicated in foodborne illness outbreaks.

On September 10, 2026, this agency closed a fourteen-person *E. coli* O157:H7 investigation, said for the first time that the food was romaine lettuce, and named no grower, no processor, no brand and no state. It said the lettuce was past its shelf life by the time investigators identified it. Twenty-one months earlier it closed an eighty-nine-person romaine outbreak that hospitalized thirty-six people, put seven into kidney failure and killed one, and named no one, for the same stated reason. In each case the government knew more than it said. The agency has named farms, processors and brands in exactly these circumstances at least eight times since 2006. What is missing is not authority. It is a written standard.

The pattern did not pause while this petition was being prepared. On October 7, 2026, the agency identified the vehicle in a thirty-eight-person *E. coli* O157:H7 outbreak it is investigating jointly with the Food Safety and Inspection Service, reference #1421 and USDA 2026-04, as “ready-to-eat multi-ingredient chicken wraps.” It said the wraps had been “proactively removed from the market before the link to the outbreak was confirmed” and were past shelf life, and it named no manufacturer, no brand, no retailer and no state. There is no recall, no advisory and no public health alert. Both agencies say



they are now looking for a contaminated ingredient and whether it went into other products.¹ By October 15 the count had risen to fifty, and the product column still read “suspect.” That day the first lawsuit in the outbreak was filed. It alleges that the wraps were Trader Joe’s Tarragon Chicken Salad Wraps and that the North Carolina health department recorded a Trader Joe’s wrap as the source of one plaintiff’s illness in its own case record. *Gottlieb v. Trader Joe’s Co.*, No. 2:26-cv-12017 (C.D. Cal. filed Oct. 15, 2026) (the petitioner is counsel for the plaintiffs). The public learned the brand from a complaint, not from either agency.

A. ACTION REQUESTED

The petitioner requests that the Commissioner take the following actions.

1. Establish by rule that the identity of an implicated firm is not confidential commercial information. Amend 21 CFR 20.61 to provide that the name and location of a firm is not confidential commercial information within the meaning of that section,² and is subject to public disclosure, where epidemiologic evidence has implicated a food in a human foodborne illness outbreak and traceback or laboratory evidence, including whole genome sequencing, identifies the firm as a likely source or point of contamination of that food. That is the same evidentiary standard item 4 applies, and the same evidence on which the agency closes an investigation.

In the same rulemaking, amend 21 CFR 20.91 to provide that the identity of the firm and the distribution and retail consignee information for a food are available for public disclosure whenever the food has been removed from commerce or corrected after the agency, the Centers for Disease Control and Prevention or a state or local health agency identified it as the suspected vehicle of a foodborne illness outbreak, whether the firm describes the removal as a recall, a market withdrawal, a stock recovery or a proactive removal, and whether or not the product remains within its shelf life. A disclosure authority that attaches only to the word “recall” can be avoided by not using the word. The companion petition filed on the same date asks the agency to confirm that such a removal is a recall under 21 CFR 7.3(g) for purposes of classification and publication of the consignee list. This request makes the disclosure authority independent of how that question is answered.

2. Write the rule with the exemption closed. Draft the provision as a rule with a stated exception rather than as a grant of discretion with an open-ended carve-out. A firm seeking to withhold its identity should bear the burden of showing, in writing and on the record, that the specific information at issue is a trade secret or is commercial information both customarily withheld and competitively sensitive apart from the fact of implication, and the agency’s decision on that showing should be published with the disclosure or the

¹ FDA, Investigations of Foodborne Illness Outbreaks, reference #1421 (linked to USDA 2026-04), table and What’s New entries of October 7 and October 15, 2026: <https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks>; FSIS, Outbreak Investigations: Response, outbreak 2026-04: <https://www.fsis.usda.gov/food-safety/foodborne-illness-and-disease/outbreaks/outbreak-investigations-response>.

² 21 CFR 20.61 (trade secrets and commercial or financial information which is privileged or confidential): <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-20/subpart-D/section-20.61>.

withholding it supports. A disclosure obligation that leaves the exemption undefined resolves the question in favor of nondisclosure for another decade.

Provide in the same rule for notice and correction. Before publication, the agency should notify the named firm and allow it a short, stated period, no longer than one business day, to identify any factual error in the information to be released, except where the agency finds that any delay would endanger health. If the agency later determines that a named firm was not a source or point of contamination, it should publish a correction in the same place and with the same prominence as the original disclosure and note the correction on the public investigations table. A firm named in error is entitled to a record that says so.

3. Reach the whole supply chain, not only the consumer-facing brand. Provide expressly that the rule reaches the grower, the harvester, the cooler, the processor, the manufacturer, the distributor, the importer and the retail or food service establishment, as the evidence identifies them. In produce outbreaks there is frequently no consumer-facing brand at all. Lettuce moves from a field to a cooler to a processor to a distributor to a kitchen and onto a plate with no logo on it at any point. A policy written around the brand name leaves precisely those outbreaks unnamed.

4. Use the authority the agency already holds, beginning now. Announce, by notice in the Federal Register or by constituent update, that the agency will exercise its authority under section 705(b) of the Act³ to name implicated firms in a public advisory whenever traceback or laboratory evidence identifies a firm as a likely source or point of contamination, whether or not product remains in commerce and whether or not a recall has occurred. That authority permits naming the firm or the product, may be exercised with or without a recall, and carries no requirement that the investigation still be open.⁴

The same subsection also provides that nothing in it prohibits the Secretary from collecting, reporting and illustrating the results of the Department's investigations. That clause does not depend on a finding of imminent danger, and it reaches the results of an outbreak investigation after the product is gone.⁵

Where an administrative enforcement action has occurred in an investigation, such as an import alert, a Form 483 or Form 4056, a warning letter or an administrative detention, or where a product or environmental isolate matches the outbreak strain by whole genome sequencing, state by interpretation that the event is an administrative enforcement action, or a predicate for one, within the meaning of 21 CFR 20.91, and disclose the identity of the firm and the distribution of its product to the extent necessary to effectuate it, whether or not a recall has occurred. The agency named the two Guatemalan growers it placed on import alert in the 2026 cantaloupe outbreak described

³ Federal Food, Drug, and Cosmetic Act section 705(b), 21 U.S.C. 375(b):
<https://www.law.cornell.edu/uscode/text/21/375>.

⁴ 21 U.S.C. 375(b). The provision contains no requirement that a recall have occurred or that an investigation remain open, and the agency has used it to name firms and products in both circumstances. See Table 1 and the sources cited there.

⁵ 21 U.S.C. 375(b) ("Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department."): <https://www.law.cornell.edu/uscode/text/21/375>.

in section III. This request asks only that the basis for that practice be stated so that it can be applied the next time. It can be granted without rulemaking.

5. Publish the facts of an open investigation and name the suspect food once traceback begins. Provide that the public investigations table will carry, for each open investigation, the epidemiologic facts the agency and the Centers for Disease Control and Prevention already compile: the number of cases, the number of states with cases, the range of illness onset dates, hospitalizations, deaths and, for Shiga toxin-producing *E. coli* investigations, cases of hemolytic uremic syndrome. These are counts, not deliberations. The Centers for Disease Control and Prevention publishes them routinely in its own outbreak notices, and this agency published them for a closed romaine outbreak in 2019.

Provide further that once the agency has initiated traceback on a specific food or commodity, the table and any associated advisory will name that food, state the date on which it was identified, identify the ingredient or ingredients under investigation where the suspect food is a multi-ingredient product, and state the agency's degree of confidence in plain terms, such as suspected, likely or confirmed. The trigger is an operational step the agency has already taken, not a working hypothesis. A suspect food named under this item identifies a food, not a firm; the naming of a firm remains governed by items 1 through 4.

Where an investigation is conducted jointly with the Food Safety and Inspection Service, apply the same standard to the FDA-regulated ingredients under investigation, and coordinate with that agency so that the public record of a single outbreak does not depend on which agency regulates the finished food.

6. State at closure whether traceback converged, and what the agency did. Provide that at the close of every investigation the public record states whether traceback converged on a single grower or processor or did not and identifies the firms if it did; whether the agency inspected, or collected product or environmental samples at, any implicated firm, and if it did neither, why not; and the case counts described in item 5.

7. Complete the transparency initiative the agency announced itself. Publish Executive Incident Summary abstracts without redaction of the identity of implicated firms, publish the standard applied to each remaining redaction, and resume the Foodborne Outbreak Overview of Data reports on a stated schedule. In September 2025 the agency committed to an abstract for every closed investigation and to retrospective reports on food and pathogen pairs linked to repeated outbreaks.⁶ The abstracts continue to appear and continue to mask distribution information. Two retrospective reports were published at launch and none since.⁷

⁶ FDA, Foodborne Illness Outbreak Executive Incident Summary Abstracts: <https://www.fda.gov/food/outbreaks-foodborne-illness/foodborne-illness-outbreak-executive-incident-summary-abstracts>.

⁷ FDA, Foodborne Outbreak Overview of Data (FOOD) Reports. Two reports are posted, both from September 2025: <https://www.fda.gov/food/outbreaks-foodborne-illness/foodborne-outbreak-overview-data-food-reports>.

8. Act expeditiously. The petitioner requests a response within the 180 days required by 21 CFR 10.30(e)(2) and asks that any interim response state what specific analysis remains and when it will be completed.⁸

B. STATEMENT OF GROUNDS

I. The petitioner

William D. Marler is the managing partner of Marler Clark, Inc., PS, a law firm whose practice is confined to foodborne illness. He has represented victims of foodborne illness since 1993 and has litigated outbreak cases involving nearly every pathogen and commodity discussed below. He represents people sickened in outbreaks in which the government has never publicly identified the firm whose product made them sick, and he has obtained through the Freedom of Information Act names the agency already held. The petitioner has an interest in the disclosure of that information, and so does every buyer, insurer, state regulator and competing grower who cannot see it today.

II. There is no published standard, and the practice has varied for twenty years

The agency's position is that the name of a company linked to an outbreak is confidential commercial information unless a recall attaches to it. Practice does not match that position. In at least eight investigations since 2006, this agency, the Centers for Disease Control and Prevention or a partner agency named the farm, the processor or the brand after the implicated product was past shelf life or otherwise out of commerce.⁹

Outbreak	Who was named	Status of the product when named
2006, <i>E. coli</i> O157:H7, Dole spinach, 205 ill and 3 dead	Natural Selection Foods as processor; the Paicines Ranch; Mission Organics as the farming company; the growers and harvesters of three other fields; the fertilizer manufacturer ¹⁰	Outbreak over; product recalled six months earlier; final report issued March 2007
2013, <i>Cyclospora</i> , salad mix	Taylor Farms de Mexico as the common supplier, and the restaurant chains ¹¹	State officials had said the salad mix was likely out of the food supply

⁸ 21 CFR 10.30 (citizen petitions), including the response requirement at 10.30(e)(2):

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-10/subpart-B/section-10.30>.

⁹ Marler Blog, FDA said the romaine was gone, so it named no grower. It has named farms, processors and brands in that exact situation before. Here are eight (Sept. 10, 2026), collecting the investigations tabulated below: <https://www.marlerblog.com/case-news/fda-said-the-romaine-was-gone-so-it-named-no-grower-it-has-named-farms-processors-and-brands-in-that-exact-situation-before-here-are-eight/>.

¹⁰ FDA and California Department of Health Services, Investigation of an *Escherichia coli* O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach (final report, March 2007):

https://www.marlerblog.com/files/2013/02/2006_Spinach_Report_Final_01.pdf.

¹¹ NBC News, FDA names Taylor Farms as source of parasite outbreak (Aug. 2013):

<https://www.nbcnews.com/healthmain/fda-names-taylor-farms-source-parasite-outbreak-6c10833090>.

Outbreak	Who was named	Status of the product when named
April 2018, <i>E. coli</i> O157:H7, whole-head romaine, Alaska	Harrison Farms of Yuma, named by the director of the agency's outbreak response office ¹²	Harvested March 5 to 16; past its 21-day shelf life; the field was in grass
July 2018, <i>Cyclospora</i> , salad mix and wraps	Fresh Express of Streamwood, Illinois, by FDA; Caito Foods and retailers by the Food Safety and Inspection Service ¹³	The expiration date of the tested package had passed, and the romaine lot had expired
December 2018, <i>E. coli</i> O157:H7, romaine	Adam Bros. Farming, Santa Barbara County, on a sediment sample from an irrigation reservoir ¹⁴	The farm had not shipped romaine since November 20
November 2021, <i>E. coli</i> O157:H7, spinach	Josie's Organics Baby Spinach ¹⁵	The best-by date of October 23 had passed before the public was told
December 2021, <i>E. coli</i> O157:H7, packaged salad	Simple Truth Organic and Nature's Basket Organic Power Greens ¹⁶	Best-by dates through December 20; traceback reached farms in two growing regions with no single production code
May 2022, hepatitis A, fresh organic strawberries	FreshKampo and HEB ¹⁷	Named while the agency stated the berries were past shelf life

Table 1. Eight investigations in which a farm, processor or brand was named after the implicated product was out of commerce or past shelf life. Sources are given in the footnotes to each entry.

¹² CIDRAP, Romaine-linked *E. coli* outbreak grows; Arizona farm named in Alaska cases (Apr. 2018): <https://www.cidrap.umn.edu/foodborne-disease/romaine-linked-e-coli-outbreak-grows-arizona-farm-named-alaska-cases>.

¹³ CIDRAP, Foodborne disease scan (Aug. 1, 2018): <https://www.cidrap.umn.edu/foodborne-disease/foodborne-disease-scan-aug-01-2018>.

¹⁴ FDA, Statement from the Commissioner and the Deputy Commissioner for Food Policy and Response on new findings (Dec. 2018): <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-fda-deputy-commissioner-frank-yiannas-new-findings>.

¹⁵ FDA, Outbreak Investigation of *E. coli* O157:H7: Spinach (November 2021): <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o157h7-spinach-november-2021>.

¹⁶ CDC, *E. coli* O157:H7 infections linked to packaged salads (Dec. 30, 2021): https://archive.cdc.gov/www_cdc_gov/ecoli/2021/o157h7-12-21/details.html.

¹⁷ FDA, Outbreak Investigation of Hepatitis A Virus: Strawberries (May 2022): <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-hepatitis-virus-strawberries-may-2022>.

Federal practice in the meat and poultry program runs the other way as a matter of routine. When product is no longer available for purchase, the Food Safety and Inspection Service issues a public health alert in place of a recall, and the alert names the establishment.¹⁸ One government, two defaults.

That default held as recently as May 2026, when the Food Safety and Inspection Service issued a public health alert for beef kofta served at The Kebab Shop restaurants, naming both the restaurant chain and the producer of beef made four months earlier and no longer available, in an *E. coli* O157:H7 outbreak in which California alone reported nine cases, five hospitalizations and two cases of hemolytic uremic syndrome.¹⁹ It did not hold in October 2026. In the joint chicken wrap investigation described above, neither agency has issued an alert or named an establishment, though the product is identified, an inspection is underway and fifty people are sick. When the agency whose routine is to name falls silent in a joint file, the absence of a written standard is no longer a problem confined to this agency's practice.

III. The reasons offered for naming do not explain the cases

Several factors appear to predict disclosure, and none holds. A positive laboratory sample explains Adam Bros., Fresh Express, Josie's and the 2006 spinach report, but Harrison Farms was named on traceback while the agency stated it had not determined how the lettuce became contaminated. The presence of a consumer brand explains why a packaged salad brand is named and its growers are not, but the 2006 report named growers, harvesters and a ranch, including fields whose samples were negative. The existence of something the public can still do, such as checking a freezer or seeking vaccination, explains the strawberry advisory, but it does not explain a final report issued six months after the product was gone.

The stated reasons have changed from case to case: in 2019 the absence of actionable information for consumers,²⁰ in 2025 the possibility that product had been frozen, and in 2026 shelf life.²¹ A decision made without a published standard can be neither predicted by the regulated industry nor reviewed by anyone. That is the defect this petition asks the agency to cure, and it can be cured without new legislation.

¹⁸ FSIS, Public Health Alert for ground beef products due to possible *E. coli* O157:H7 (Apr. 2024), stating that a recall was not requested because the product was no longer available: <https://www.fsis.usda.gov/recalls-alerts/fsis-issues-public-health-alert-ground-beef-products-due-possible-e--coli-o157h7-o>.

¹⁹ FSIS, Public Health Alert for Beef Kofta Products Served at The Kebab Shop Restaurant Locations Due to Possible *E. coli* O157:H7 Contamination (May 2026), naming Olympia Food Industries, Inc. as the producer of raw ground beef produced January 6, 2026 and stating that a recall was not requested because the products were no longer available: <https://www.fsis.usda.gov/recalls-alerts/fsis-issues-public-health-alert-beef-kofta-products-served-kebab-shop-restaurant>.

²⁰ Food Poison Journal, Romaine *E. coli* outbreak happened in September, and no one told you (Nov. 2019): <https://www.foodpoisonjournal.com/foodborne-illness-outbreaks/romaine-e-coli-outbreak-happened-in-september-and-no-one-told-you/>.

²¹ Marler Blog, FDA now says, Romaine calm. Romaine lettuce caused a summer 2026 *E. coli* O157:H7 outbreak (Sept. 10, 2026): <https://www.marlerblog.com/case-news/fda-now-says-romaine-calm-romaine-lettuce-caused-a-summer-2026-e-coli-o157h7-outbreak-it-waited-until-it-closed-the-file-and-it-named-no-grower-and-no-processor/>.

The agency's own 2026 record shows the inconsistency in a single year. In the *Salmonella* Newport outbreak linked to cantaloupe imported from Guatemala, reference #1366, seventy people fell ill in twenty-five states. The agency said the product was likely past shelf life and off the market. Even so, the importer, Ayco Farms, Inc. of Pompano Beach, Florida, recalled a lot of whole cantaloupe on March 24, 2026, so that downstream customers would not further process it, the agency placed two Guatemalan growers on import alert, and all three firms were named. Later the same year, in reference #1382, romaine lettuce past its shelf life produced no recall and no name. The difference between the two was not shelf life. It was whether a recall happened to attach. And the executive summary for the cantaloupe outbreak, released in September, still redacts the states with cases and the names and locations of other firms in the traceback.²²

IV. Three recent investigations show what the present practice costs

Reference #1280. In the fall of 2024, an *E. coli* O157:H7 outbreak linked to romaine sickened 89 people in 15 states, hospitalized 36, caused seven cases of hemolytic uremic syndrome and killed one person.²³ The agency closed the investigation with the word romaine and nothing further. When the traceback summary was first released, the processor, the grower and the ranch were redacted. Released later without redaction, in stages and only after three firms in the supply chain signed authorizations consenting to release of their own information, the same document showed that traceback had converged on a single processor and a single grower.²⁴ The information existed inside the government throughout. The public obtained it through records requests, more than a year later, after the season, the product and any chance of consumer action had passed. One firm identified in that traceback has publicly denied that its product was the source, which is a further reason for contemporaneous disclosure on the record rather than disclosure by increments through litigation.

Reference #1382. On September 10, 2026, the agency closed a fourteen-person *E. coli* O157:H7 investigation and stated for the first time that romaine lettuce was the likely source, adding that the product was beyond shelf life by the time investigators identified it.²⁵ The closed row shows traceback initiated, no agency inspection, no agency sampling and no recall. The closure does not state how many states had cases, how many people were hospitalized, whether anyone developed hemolytic uremic syndrome, when investigators settled on romaine, or whether traceback converged on one grower and one

²² FDA, Executive Incident Summary Abstract, *Salmonella* Newport, cantaloupe, reference #1366: <https://www.fda.gov/media/194838/download>; Food Safety News, Cantaloupe outbreak declared over (May 14, 2026): <https://www.foodsafetynews.com/2026/05/cantaloupe-outbreak-declared-over/>.

²³ Marler Blog, CDC and FDA romaine silent, collecting the published case counts for reference #1280: <https://www.marlerblog.com/case-news/cdc-and-fda-romaine-silent/>.

²⁴ Marler Blog, The 2024 romaine *E. coli* outbreak had a name the whole time: <https://www.marlerblog.com/case-news/the-2024-romaine-e-coli-outbreak-had-a-name-the-whole-time-the-fda-just-would-not-say-it-transparency-should-not-be-an-option/>.

²⁵ FDA, Investigations of Foodborne Illness Outbreaks (the CORE investigations table), reference #1382, closed September 10, 2026: <https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks>.

processor or fanned out across many. For ten weeks the only public record of this outbreak was a single row reading Not Yet Identified.

Both omissions, the case counts and the traceback result, are curable at no cost, and the agency has answered these questions before on the same facts. In October 2019 it announced a twenty-three-person romaine outbreak that had already ended, with the product past shelf life, and published case counts in twelve states, eleven hospitalizations and its reason for making the announcement. Nothing in the statute changed between 2019 and 2026.

Reference #1421. The chicken wrap investigation shows the same practice operating while an outbreak is still open. The row was posted on September 23, 2026, with twenty-five cases and the product listed as not yet identified. On September 30 it showed thirty-eight cases and sampling underway. On October 7 it named the suspect vehicle as a multi-ingredient wrap with chicken and showed an inspection initiated. On October 15 it showed fifty cases, with the product still listed as suspect. At no point has the public record stated the states with cases, the onset dates, the number hospitalized, the number with hemolytic uremic syndrome, the brand, the retailer or the ingredient under investigation. That is progress of the kind item 5 asks for, a suspect food named while the file is open, stopped one step short of usefulness. A person who ate a chicken wrap in September cannot tell from a category whether it was the one under investigation; neither can that person's physician or the health department interviewing them; and a buyer of the ingredient under investigation cannot learn which ingredient it is.

V. The legal authority for the requested rule is already in place

The Trade Secrets Act forbids disclosure of confidential commercial information only where disclosure is not authorized by law.²⁶ Two authorizations already exist. The first is 21 CFR 20.91, which provides that data and information otherwise exempt from public disclosure are nevertheless available for disclosure to the extent necessary to effectuate an administrative or court enforcement action, and which gives as its own example the release of brand name, code designation and distribution information when a product is recalled.²⁷ The second is section 705(b) of the Act, which authorizes dissemination of information regarding food in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer, and which the agency has used to name firms and products with and without a recall. The statute defining the agency's mission also directs it to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled.²⁸

Those authorizations have limits, and the petitioner states them. The agency has named consumer-facing brands without a recall, but it has treated the identity of supply-chain firms as confidential commercial information. The authorization in 20.91 is tied by its terms to an administrative or court enforcement action, and its only example is a recall, a term the agency's recall regulations define to exclude a market withdrawal or a stock

²⁶ Trade Secrets Act, 18 U.S.C. 1905: <https://www.law.cornell.edu/uscode/text/18/1905>.

²⁷ 21 CFR 20.91: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-20/subpart-E/section-20.91>.

²⁸ 21 U.S.C. 393(b)(2)(A): <https://www.law.cornell.edu/uscode/text/21/393>.

recovery.²⁹ When no recall or other enforcement action has occurred, the agency has not treated 20.91 as available. And the imminent-danger trigger in section 705(b) is framed in the present tense, which the agency may read to lapse once the response phase ends and the product is gone. The petitioner takes those limits as the reason for this petition, not an obstacle to it. Item 4 rests on the parts of section 705(b) that do not depend on imminent danger, and on 20.91 where an enforcement action has occurred. Item 1 rests on neither. It rests on section 701(a) of the Act, 21 U.S.C. 371(a), and the agency's authority under it to define by rule what it treats as confidential commercial information under 20.61, and on the case law, discussed in section VI, holding that a business name is not commercial information in itself. Items 1 through 3 remain necessary in any event, because a discretionary practice is undone by the next decisionmaker, while a published rule with a stated exception can be applied, measured and reviewed.

VI. The counterarguments, stated fairly and answered

The first and strongest argument against this petition is that the Supreme Court has read the fourth exemption of the Freedom of Information Act broadly, so that commercial information customarily kept private and supplied to the government under an assurance of privacy is confidential for purposes of that exemption.³⁰ There are three answers. The first is that the exemptions to the Freedom of Information Act are permissive rather than mandatory. They authorize withholding in response to a request; they do not forbid affirmative disclosure.³¹ What forbids disclosure is the Trade Secrets Act, and that statute reaches only disclosures not authorized by law. The same decision holds that a regulation supplies that authorization only if it is substantive, rests on a congressional grant of authority, and was issued in compliance with procedural requirements. That is why the petitioner asks for notice-and-comment rulemaking, the procedure by which 20.91 itself was adopted, rather than a change in practice. The petitioner also acknowledges that, after *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), a court will not defer to the agency's reading of the fourth exemption itself. The requested rule does not depend on deference. It does not ask a court to accept that a name falls outside the exemption because the agency says so; it supplies the authorization by law that the Trade Secrets Act requires, which is the question Chrysler answers. Nor does section 301(j) of the Act, 21 U.S.C. 331(j), stand in the way. It protects information concerning a method or process that is entitled to protection as a trade secret, and the name and location of a firm is neither.

The second answer is that a firm's name is not commercial information in its own right. Considering for the first time whether the fourth exemption reaches a business's name, the D.C. Circuit held that information must be commercial in and of itself, and that the prospect that disclosure would expose a firm to public hostility and resulting economic

²⁹ 21 CFR 20.91 (disclosure to the extent necessary to effectuate an administrative or court enforcement action, with recall as the stated example); 21 CFR 7.3(g), (j), (k) (defining recall to exclude market withdrawals and stock recoveries): <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7/subpart-A/section-7.3>.

³⁰ *Food Marketing Institute v. Argus Leader Media*, 588 U.S. 427 (2019).

³¹ *Chrysler Corp. v. Brown*, 441 U.S. 281, 290–94, 301–03 (1979).

harm does not make a name commercial.³² That is precisely the harm a firm implicated in an outbreak fears. The court also observed that most businesses publicize their names rather than keep them private. The third answer is that the assurance of privacy on which the Supreme Court relied can be withdrawn prospectively. The Department of Justice has advised agencies that information submitted with an express or implied indication that the government would disclose it is not confidential.³³ A published rule supplies that indication for every investigation that follows it.

The petitioner acknowledges the contrary authority. On remand in the same case, the district court held that the contractors' names were commercial because their disclosure would reveal sales to the government and partially reveal customer lists, while noting that confidentiality had been conceded and that the case arose from a government contract.³⁴ A 2025 decision ordering disclosure of the purchasers of tobacco grown by employers that had violated federal labor law left open whether the purchasers themselves treat their identity as confidential.³⁵ Neither case involved a public health investigation, and neither involved a regulation authorizing disclosure. The agency's own regulations add one further point. Section 20.82(b)(1) excludes trade secrets and confidential commercial information from the Commissioner's general discretion to release records in the public interest.³⁶ That limit is the reason the petitioner asks for a rule rather than an exercise of discretion.

Even within the Freedom of Information Act, withholding is no longer automatic. Since 2016 the Act has permitted an agency to withhold information only where it reasonably foresees that disclosure would harm an interest protected by an exemption, or where disclosure is prohibited by law.³⁷ The Second Circuit, in a case against this agency, held that the requirement imposes an independent burden in Exemption 4 cases, one the agency must meet with a specific showing tied to the information withheld.³⁸ The court found that burden met on the record before it, which involved detailed commercial information about a drug sponsor's product, not the bare name of a firm. A firm's generalized concern that association with an outbreak will cost it business is the harm the D.C. Circuit has already held does not make a name commercial, and it is not the specific showing the statute now requires.

The second argument is that a firm may be named in error and injured by the naming. The petitioner states the leading example against his own position. In June 2008, during

³² *Citizens for Responsibility & Ethics in Washington v. U.S. Department of Justice*, 58 F.4th 1255, 1265–68 (D.C. Cir. 2023).

³³ U.S. Department of Justice, Office of Information Policy, Exemption 4 after the Supreme Court's Ruling in *Food Marketing Institute v. Argus Leader Media*: <https://www.justice.gov/oip/exemption-4-after-supreme-courts-ruling-food-marketing-institute-v-argus-leader-media>.

³⁴ *Citizens for Responsibility & Ethics in Washington v. U.S. Department of Justice*, 728 F. Supp. 3d 113, 122–23 (D.D.C. 2024).

³⁵ *Farm Labor Organizing Committee v. U.S. Department of Labor*, 2025 U.S. Dist. LEXIS 143974, at *9–11 (D.D.C. July 28, 2025).

³⁶ 21 CFR 20.82(b)(1): <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-20/subpart-E/section-20.82>.

³⁷ 5 U.S.C. 552(a)(8)(A)(i): <https://www.law.cornell.edu/uscode/text/5/552>.

³⁸ *Seife v. U.S. Food & Drug Administration*, 43 F.4th 231, 239–42 (2d Cir. 2022).

a *Salmonella* Saintpaul outbreak, the agency warned consumers against certain raw tomatoes. The outbreak was later traced to jalapeño and serrano peppers grown in Mexico, and tomato growers lost a season of sales. Growers sued the United States, and the Federal Circuit rejected their claims.³⁹ The government’s legal exposure is therefore low. The episode remains the right caution, and this petition is written around it. The 2008 warning was a commodity advisory issued while the investigation was open on epidemiologic association. Items 1 through 4 and 6 attach the naming of a firm to traceback convergence or laboratory evidence, the same evidence on which the agency closes an investigation, and not to a working hypothesis. The one exception, the 20.91 amendment in item 1, attaches to a removal the firm itself has already undertaken because its product was identified as the suspected vehicle, a step that has already associated the firm with the outbreak in the eyes of every customer it notified. Item 5 names a suspect food, not a firm, and only once traceback has begun, with the degree of confidence stated. The notice and correction requirements in item 2 give a firm named in error a prompt public remedy the tomato growers never had. The agency already manages a larger version of this risk every time it issues a commodity-wide consumer advisory. The alternative to naming is not the absence of injury. It is the distribution of one firm’s injury across every grower of the commodity.

The third argument is that section 705(b) speaks of imminent danger to health, and that no imminent danger remains once a product is past its shelf life. That reading would bar most of the eight disclosures in Table 1. It reads out the statute’s words “in the opinion of the Secretary,” which commit the judgment of imminent danger to the agency rather than to the shelf-life date. It also overlooks the provision’s final sentence, which preserves the Secretary’s authority to report the results of the Department’s investigations without any finding of danger. And it overlooks the people already sick, whose physicians and health departments need the identity of the food to diagnose, interview and count. The rule requested in item 1 does not rest on section 705(b) at all; it rests on the agency’s rulemaking authority to define what it treats as confidential commercial information under 21 CFR 20.61.

VII. Anonymity moves the cost onto firms that did nothing wrong

When the government identifies a commodity and stops, consumers avoid the commodity. During the 2026 *Cyclospora* outbreak, Numerator data reported that 6.5 million households stopped buying salad mixes and kits in a single month.⁴⁰ That cost fell on every grower and processor in the category, including those whose product was never implicated and whose practices were never in question. A firm-specific disclosure is the only instrument that distinguishes them. The produce industry has more to gain from a published standard than any other party to this petition, because under the present practice its members can neither clear themselves nor learn from one another.

³⁹ DiMare Fresh, Inc. v. United States, 808 F.3d 1301 (Fed. Cir. 2015); Seaside Farm, Inc. v. United States, 842 F.3d 853 (Fed. Cir. 2016).

⁴⁰ Grocery Dive, *Cyclospora* outbreak hits produce sales (Aug. 2026), reporting Numerator household purchase data: <https://www.grocerydive.com/news/cyclospora-outbreak-produce-sales-numerator/828345/>.

VIII. Disclosure is a prevention tool, not a punishment

The identity of an implicated firm is the fact that allows a buyer, an insurer, a state regulator, a competitor or a jury to connect this outbreak to the last one. Two remain investigations that closed without a name were later connected to the same processor through records obtained afterward. Withhold the name and every outbreak arrives looking like the first one anyone has ever had. Publish it and a purchasing department can weigh a supplier's history, an insurer can price it, a board can act on it, and the firm acquires a reason to find the problem before the next season. That is transparency operating on the incentive rather than on the offense, and it reaches firms an enforcement action will never touch.

IX. The investigations table withholds what the agency already knows

The public table routinely lists the food as not yet identified while traceback, sampling and inspection are underway, which means the agency frequently knows more than the table says. As of October 15, 2026, the table carried fifteen active investigations, nine of which named no food at all. Those nine accounted for 626 illnesses, and four of them, with 184 illnesses among them, were outbreaks the table still listed as ongoing. In August the table carried seventeen open investigations. A produce buyer who cannot learn what commodity is suspected cannot act on it, and neither can a hospital cafeteria, a school district or a distributor.

Two complaints about this reflex arrive from opposite ends of the supply chain. Consumer organizations report that disclosure is too narrow and too late. Produce buyers report that they cannot find out what is suspected in time to act on it. Both describe the same institutional instinct, and the same rule answers both.

X. States already publish what the federal record withholds

State agencies regularly identify firms, products and retail locations in outbreaks in which the federal record names no one. Washington identified an implicated creamery and the specific cheeses by name during an open investigation in 2025.⁴¹ California has published the names and locations of retail stores that received implicated product in the September 2026 Happy Hens egg outbreak in San Diego County. Federal silence in these circumstances protects nothing. It produces a public record that is incomplete, inconsistent from state to state, and unusable by a national buyer.

XI. The agency has changed a confidentiality default before, by this same route

In 2018 the agency concluded that publication of retail consignee lists is necessary in certain circumstances to effectuate a recall and therefore authorized under 21 CFR 20.91,

⁴¹ Washington State Department of Health, 2025 outbreak of Shiga toxin-producing *E. coli* infections linked to Twin Sisters Creamery aged raw milk cheese. The petitioner represents a claimant in that matter: <https://doh.wa.gov/you-and-your-family/illness-and-disease-z/foodborne-illness/outbreaks/2025-outbreak-shiga-toxin-producing-e-coli-stec-infections-linked-twin-sisters-creamery-aged-raw>.

and it issued guidance to that effect, finalized in November 2020.⁴² That decision establishes two things relevant here. The agency can revisit a longstanding confidentiality position without new legislation, and 20.91 is the vehicle by which it does so. The episode also shows the limit of guidance: the resulting policy states what the agency intends to do, is directed principally at foods that are not easily identified from their packaging and remain available for consumption, and binds no one. The petitioner is filing, on the same date, a companion petition asking that the consignee policy be written as a regulation on the model the Food Safety and Inspection Service adopted in 2008.⁴³

XII. The pending petition, and why this one is necessary

Stop Foodborne Illness petitioned the agency on February 4, 2026, to change its position that a company name is confidential commercial information, or in the alternative to disclose the name of a company linked to an outbreak in reliance on the agency's statutory responsibility to ensure safe food or by revising 21 CFR 20.91.⁴⁴ On July 28, 2026, the agency issued an interim response stating that it had been unable to reach a decision because the petition raises complex issues requiring extensive review and analysis by agency officials.⁴⁵ The petitioner supports that petition and asks that it be granted.

This petition does not duplicate it. It asks for four things the pending petition does not reach, none of which depends on how the agency resolves the confidential commercial information question: a rule written with the exemption closed, the burden placed on the firm and a correction required when a named firm is cleared; express coverage of growers, processors and distributors in outbreaks with no consumer-facing brand; use of section 705(b) and 20.91 in the interval; and publication of the operational record, meaning the suspect commodity while an investigation is open, the closure facts, the unredacted abstracts and the resumption of the retrospective reports. Each can be granted whether or not the agency changes its reading of 20.61.

XIII. Pending legislation confirms the gap and does not fill it

On September 28, 2026, the Senate passed S. 4974, the Making America's Food Safer Act. Section 3(a) of the bill would add a subsection (e) to section 708 of the Act authorizing the Secretary to disclose commercial information otherwise protected by the Trade Secrets Act when disclosure advances public health protection during a food safety incident, including a foodborne illness outbreak, an investigation related to contaminated

⁴² FDA, Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls (final guidance, November 2020): <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/public-availability-lists-retail-consignees-effectuate-certain-human-and-animal-food-recalls>.

⁴³ Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls, final rule (July 17, 2008), codified at 9 CFR 390.10: <https://www.govinfo.gov/content/pkg/FR-2008-07-17/pdf/E8-16221.pdf>.

⁴⁴ Stop Foodborne Illness, Citizen Petition (Feb. 4, 2026), Docket No. FDA-2026-P-1448: <https://stopfoodborneillness.org/wp-content/uploads/2026/02/STOP-FDA-HHS-CCI-Petition-Final-2.4.2026.pdf>.

⁴⁵ Letter from the Director, Coordinated Outbreak Response and Evaluation Network, FDA Human Foods Program, to Stop Foodborne Illness, Re: Docket No. FDA-2026-P-1448 (July 28, 2026). Docket record: <https://www.regulations.gov/docket/FDA-2026-P-1448>.

food, or a food recall.⁴⁶ The bill confirms that Congress sees the gap this petition describes. It is not a reason to defer the petition. The bill has not been enacted. If it is enacted, proposed section 708(e) authorizes disclosure without requiring it, and it defines neither a food safety incident nor what it means for disclosure to advance public health protection. The agency would still need a written standard stating which firms are named, on what evidence, when, and with what opportunity for correction. The rule requested here is that standard. It can be adopted under existing authority now, and it will serve as the implementing rule if the bill becomes law.

XIV. What the requested rule would cost

The government's cost is the drafting of a rule and the editing of documents it already publishes. The information sought is collected in the ordinary course of an outbreak investigation, recorded in traceback files and inspection records, and in many instances already published by a state agency. There is no new sampling, no new inspection and no new system. The agency has not met the domestic food facility inspection frequencies mandated by the FDA Food Safety Modernization Act since fiscal year 2018,⁴⁷ which is a further reason to prefer a measure that costs almost nothing over any measure that requires people in the field.

One further piece of evidence sits in the agency's own files. The Executive Incident Summary abstract for reference #1339 states that traceback legs converged on a supplier and processor of packaged organic salads and redacts the name and even the number of legs.⁴⁸ The analysis was done. The conclusion was reached. What is missing is the name, and the rule that would require it.

XV. Conclusion

This agency has named farms, processors and brands after the product was gone at least eight times, and declines to do so now, including this month, for fifty people sickened by chicken wraps whose maker it has not named. It holds authority to disclose now, and authority to write by rule the standard that would make disclosure routine. It has already changed one confidentiality default by this same route. A family whose child spent nine days on dialysis should not have to file a records request to learn whose lettuce it was, and a grower who did everything right should not pay for a competitor's outbreak because the government would not say a name. Everything needed to write this rule is in the agency's files. What is missing is the rule.

C. ENVIRONMENTAL IMPACT

The petitioner claims a categorical exclusion under 21 CFR 25.30(h), which covers the issuance or amendment of procedural or administrative regulations. To the petitioner's knowledge, no extraordinary circumstances exist under 21 CFR 25.21. The action

⁴⁶ S. 4974, 119th Cong. § 3(a) (as passed by the Senate, Sept. 28, 2026):
<https://www.congress.gov/bill/119th-congress/senate-bill/4974>.

⁴⁷ GAO-25-107571, Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply (Jan. 8, 2025): <https://www.gao.gov/products/gao-25-107571>.

⁴⁸ FDA, Executive Incident Summary Abstract, reference #1339:
<https://www.fda.gov/media/190906/download>.

requested concerns the disclosure of information and does not individually or cumulatively have a significant effect on the human environment. It involves no approval or marketing of any product and no construction or modification of any facility.⁴⁹

D. ECONOMIC IMPACT

Information on economic impact will be submitted upon request of the Commissioner in accordance with 21 CFR 10.30(b). The petitioner notes that the action requested imposes no compliance cost on any regulated firm. It requires no testing, no reformulation, no labeling change and no new recordkeeping. The only costs are the agency's own drafting and publication costs, which are modest, and the reputational consequence to a firm whose product has been implicated in human illness, which follows from information the public is entitled to have.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



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⁴⁹ 21 CFR part 25 (environmental impact considerations; categorical exclusions):
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-25>.

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