

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

)	
PUBLIC EMPLOYEES FOR)	
ENVIRONMENTAL RESPONSIBILITY,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.: 18-2219 (BAH)
)	
UNITED STATES ENVIRONMENTAL)	
PROTECTION AGENCY,)	
)	
Defendant.)	
)	

**DEFENDANT’S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT
AND OPPOSITION TO PLAINTIFF’S CROSS-MOTION FOR SUMMARY JUDGMENT**

On July 9, 2018, Plaintiff, Public Employees for Environmental Responsibility, submitted a request pursuant to the Freedom of Information Act (“FOIA”) seeking explicitly any versions of the existing “draft” formaldehyde assessment. When those drafts were withheld by Defendant, U.S. Environmental Protection Agency (“EPA”), as protected from disclosure by the deliberative process privilege under FOIA Exemption 5, Plaintiff selected one particular, representative draft to challenge before this Court (the “Withheld Draft Assessment”). The record before the Court plainly demonstrates that the Withheld Draft Assessment is a redlined draft reflecting preliminary deliberations and judgments of EPA staff that is at the early stages of a process which would result in a final assessment of the health effects of formaldehyde and contribute to EPA’s broader policy-making and decision-making on environmental and health risks of formaldehyde. It is, not surprisingly, a document that is both “predecisional” and “deliberative,” as required by the deliberative process doctrine. Its premature disclosure, which Plaintiff seeks to force through this

litigation,¹ would result in foreseeable harms in the form of discouraging candid agency analysis and creating public confusion regarding the health effects of formaldehyde and EPA's position on those effects. Accordingly, EPA respectfully requests that the Court grant its motion for summary judgment and deny Plaintiff's cross-motion.

FACTUAL BACKGROUND

A. Relevant Formaldehyde Assessment History

In 2010, EPA released an earlier draft toxicological assessment of formaldehyde ("2010 Assessment") for public comment. The 2010 Assessment was released for public comment consistent with Step 4 of the seven-step IRIS process for developing chemical toxicity assessments, after having completed internal agency review and interagency review. Second Declaration of Dr. Jennifer Orme-Zavaleta ("2d Orme-Zavaleta Decl.") ¶ 4. Plaintiff now contends that there is currently another draft formaldehyde assessment at IRIS Step 4, citing a GAO report that states "according to the 'IRIS Assessments in Development' website, [the Formaldehyde Assessment] was at Step 4 of the IRIS process." Opp. at 9, 11, 13, 21, 23, 31. The cited website, however, was referring to the 2010 Assessment, not the current draft formaldehyde assessment. 2d Orme-Zavaleta Decl. ¶ 5. The 2010 Assessment remains available on EPA's website. *Id.*

After significant comments were received from a National Academy of Sciences ("NAS") peer review concerning the 2010 Assessment, EPA never finalized the 2010 Assessment. *Id.* ¶ 6.

¹ Plaintiff is upfront that its FOIA litigation is meant not simply to obtain non-exempt public records but to force or "secure the release of a study" on formaldehyde toxicity that it believes EPA should have made public. Memorandum in Support of Plaintiff's Cross-Motion and Opposition to Defendant's Motion for Summary Judgment ("Opposition" or "Opp.") at 1 (ECF No. 23).

As stated in the first Orme-Zavaleta Declaration, EPA began work on this iteration of the formaldehyde assessment in 2014 (referred to herein in as the “Current Draft Assessment”).² Orme-Zavaleta Decl. ¶ 7 (ECF No. 21-2). This action was publicly disclosed in June 2015. According to a June 2015 update from the IRIS Program on its various chemical assessments, to address the 2011 NAS peer review recommendation, EPA was working on a new assessment that would “repeat Agency review and interagency science consultation before being released” for public comment and discussion. 2d Orme-Zavaleta Decl. ¶ 6, Ex. A. The internal and interagency reviews are Steps 2 and 3 of the IRIS process. Orme-Zavaleta Decl. ¶ 8. As reflected in this IRIS update, the Current Draft Assessment was at Step 1, and it has not moved past that step to this day. 2d Orme-Zavaleta Decl. ¶ 7.

Repeatedly in its Opposition, Plaintiff misleadingly asserts that Administrator Pruitt had stated that the IRIS formaldehyde assessment was complete.³ Specifically, Plaintiff cites testimony of Administrator Pruitt on January 30, 2018, before the U.S. Senate Committee on the Environment and Public Works, but draws a conclusion unsupported by that testimony.⁴ The full Q&A is as follows:

² For clarity, this brief refers to (1) the 2010 Assessment, which was publicly released and never finalized; (2) the Current Draft Assessment, which refers to any version the draft assessment reflecting the current iteration of the IRIS formaldehyde assessment process; and (3) the Withheld Draft Assessment, which is the selected version of the Current Draft Assessment that is being litigated.

³ *See, e.g.*, Opp. at 25 (“EPA Administrator had announced that the Assessment was complete and would be released for public review”), 39 (“The Formaldehyde Assessment was completed in all but name in 2018, according to the EPA Administrator[.]”).

⁴ U.S. Senate Comm. on Env't. & Pub. Works, S. HRG. 115–325; Volume 1, Oversight Hearing to Receive Testimony from Environmental Protection Agency Administrator Scott Pruitt 278 (Jan. 30, 2018), available at <https://www.govinfo.gov/content/pkg/CHRG-115shrg30599/pdf/CHRG-115shrg30599.pdf>.

Senator MARKEY. Thank you, Mr. Chairman; I appreciate it. Mr. Pruitt, it is my understanding that the EPA has finalized its conclusion that formaldehyde causes leukemia and other cancers, and that that completed new assessment is ready to be released for public review. But it is still being held up. Can you give us a status update as to the EPA's handling of the formaldehyde issue and the conclusion that it in fact does cause leukemias and other cancers?

Mr. PRUITT. My understanding is similar to yours, but I will confirm that and provide the information to you from the program office.

Senator MARKEY. Will you commit to releasing that report, which is already completed, in a short period of time once you have reviewed it, if in fact meets the standards which your EPA staff has already established that it does cause——

Mr. PRUITT. Senator, I commit to you that I will look into that and make sure your office is aware of what we have and when we can release it.

The testimony establishes that Senator Markey thought that a new formaldehyde assessment was complete and ready for public review. Administrator Pruitt, on the other hand, testified in response to Senator Markey's compound question that he needed to confirm the status of the assessment and get back to Senator Markey.⁵ Furthermore, Administrator Pruitt's testimony does not contradict Dr. Orme-Zavaleta's Declaration that the Current Draft Assessment is at Step 1 of the IRIS process.

Plaintiff's reliance on reporting of a January 24, 2018, meeting between representatives of the American Chemistry Council's Formaldehyde Panel ("ACC Panel") and EPA staff, also fails to support its belief that there is a "complete" ready-to-be-published formaldehyde assessment. Dr. Orme-Zavaleta was present at this meeting and confirms that no draft of the formaldehyde

⁵ Plaintiff's belief in the existence of a "final" assessment is further undermined by Administrator Pruitt's response to the Senate Committee's written questions. When asked for an "un-redacted copy of the current draft of the IT IS human health assessment for formaldehyde," the response was: "The Agency does not release any products that have not undergone proper quality review." *See supra* at 8, n.4.

assessment was shared at that meeting with ACC Panel and that EPA did not share any information substantial enough to amount to a disclosure of the draft assessment. *Id.* ¶ 9.

Plaintiff also cites a July 6, 2018, article in Politico, but that article actually contradicts Plaintiff's belief that there is now or was at that time a completed formaldehyde assessment. In fact, Plaintiff's cited article states that the formaldehyde draft assessment had not "beg[un] the required internal review" and was "at the first step of the IRIS review process."⁶ Indeed, Plaintiff admits that it submitted its FOIA request "three days after Politico reported" on a "draft at the first step of the IRIS review process." *Opp.* at 10. By letter dated July 9, 2018, Plaintiff submitted a FOIA request (the "Request") to EPA seeking, among other records, "[a]ny versions of [formaldehyde] draft health assessment EPA, prepared between January 1, 2015, to present, regarding the possible carcinogenic or other health harms of day-to-day formaldehyde vapor inhalation." Orme-Zavaleta Decl., Exhibit A.

B. Litigation History

EPA communicated directly and extensively with Plaintiff throughout the litigation process, including reaching agreement on the Agency's search plan and developing a mutually agreeable production schedule. *See* Declaration of Kevin Bell ("Bell Decl."), Ex. 1 (ECF No. 23-1). As is typical in FOIA cases, EPA included a "withholdings index" in the Agency's final production on July 18, 2019. *Id.*, Ex. 1 at 1. The index provided by EPA was not a *Vaughn* index, which has particular requirements as set forth in *Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973).

⁶ Sources: EPA blocks warnings on cancer-causing chemical, POLITICO (July 6, 2018), <https://www.politico.com/story/2018/07/06/epa-formaldehyde-warnings-blocked-696628>. Other articles cited by Plaintiff similarly fails to support the argument made in its Opposition that there was a completed draft formaldehyde assessment. *See Opp.* at 9.

The emails attached to the Bell Declaration tell the story of how the parties arrived at briefing the Withheld Draft Assessment. After EPA completed its production in July 2019, Plaintiff wrote on September 21, 2019: “I think the way we’re planning on resolving the case is to pick one of the withheld versions of the IRIS report. . . . That might well end up going to briefing[.]” *Id.*, Ex. 3 at 6. Plaintiff’s counsel also stated “I can dig through the produced emails again to find a specific attachment file[.]” *Id.*

EPA understood Plaintiff’s statements to mean that to resolve this case Plaintiff would identify a particular withheld version of the records for further analysis, and perhaps eventually brief, as evidenced by EPA’s November 7, 2019 email to that effect, asking Plaintiff if “you identified a particular record or records for [EPA] to look into further[.]” *Id.*, Ex. 3 at 4. In response the same day, consistent with its September 21 statement, Plaintiff specifically volunteered to “pick a file.” *Id.* In that message and since that date, Plaintiff has not sought EPA’s input on which record to choose. *Id.*, Ex. 3 at 1-4.

On December 6, 2019, Plaintiff identified a particular record: “I think that the cleanest file of the many attachments is “Formaldehyde Main Text 102417 06-13-18.docx” which is marked as ED_002316G_00008896 in the withholdings index.” *Id.*, Ex. 3 at 3. It was chosen because it was the “most recently dated . . . to be of sufficient length (over 500 pages) and whose filename” did not suggest it was a personal draft. *Id.* ¶ 16. After Plaintiff chose the document, EPA reviewed the 700-plus page document “to assess for any potential segregability.” *Id.*, Ex. 3 at 2. After that review was completed, EPA “decided to continue to withhold ED_002316G_00008896 in full under Exemption 5 as deliberative.” *Id.*, Ex. 3 at 1.⁷

⁷ The process through which the parties came to identify a single document for challenge is memorialized in the parties’ status reports. On November 14, 2019, the parties reported: “Since

As Exhibit 3 to the Bell Declaration shows, Plaintiff never asked EPA whether the record Plaintiff had chosen contained any redlined edits or comments. Plaintiff contends that it “asked EPA to perform a review of a specific draft . . . to determine if it was reasonably ‘clean’ of tracked changes or author comments.” Opp. at 11. But that request did not occur, as reflected in the email correspondence. Plaintiff further asserts that EPA “consistently refused to provide PEER with even enough information to meaningfully distinguish” between different versions of withheld draft assessments. Opp. at 12. That also is incorrect. A refusal requires a specific request, and such a request was not made, again as reflected in the email correspondence. Neither the text of the Bell Declaration nor the exhibits thereto support the unfounded assertions made in Plaintiff’s brief.

ARGUMENT

The Opposition offers nothing to undermine EPA’s use of Exemption 5, and specifically the deliberative process privilege, to withhold the draft formaldehyde assessment at issue. The Withheld Draft Assessment is “predecisional” and “deliberative,” thereby satisfying the requirements of the privilege. *Pub. Citizen, Inc. v. Off. of Mgmt. & Budget*, 598 F.3d 865, 874 (D.C. Cir. 2009). Furthermore, foreseeable harm will result should the Withheld Draft Assessment be disclosed prior to completion of the formaldehyde assessment process.

the last Joint Status Report (ECF No. 15), the parties have engaged in discussions to attempt to either settle or narrow the issues in dispute to a single representative record. The discussions are ongoing, and the parties require additional time for review before proposing a briefing schedule.” ECF No. 16. By Minute Order dated January 13, 2020, this Court ordered “the parties to file, by March 13, 2020, a joint status report advising the Court of any issues in dispute and proposing a schedule for dispositive briefing.” On March 13, 2020, the parties jointly reported that they “were unable to resolve their dispute over the application of FOIA exemption 5” and that they “agreed to narrow the subject of their dispute on summary judgment to that document, entitled “Formaldehyde Main Text 102417 06-13-18.docx,” marked as in the withholdings index.” ECF No. 19.

The weakness of Plaintiff’s arguments concerning the Withheld Draft Assessment is reflected in its new effort to make the dispute about documents other than the one selected representative draft assessment. Plaintiff has arguably waived its right to challenge other withheld documents or aspects of EPA’s FOIA response. *See* Litigation History, *supra*. But regardless, Plaintiff is now seeking a version of the assessment that does not exist. 2d Orme-Zavaleta Decl. ¶¶ 3-7. There is no “final” or “ready-to-be-published” version of the Current Draft Assessment that Plaintiff can run to because the Withheld Draft Assessment is properly exempt from disclosure.

I. The Withheld Draft Assessment Is Predecisional

EPA established that the Withheld Draft Assessment is a predecisional document. *See* Mem. in Support of Def. Mot. for Summ. J. (“Mem.”) at 5-7 (ECF No. 21). “A document is predecisional if it was ‘prepared in order to assist an agency decision maker in arriving at his decision,’ rather than to support a decision already made.” *Petroleum Info. Corp. v. Dep’t of Interior*, 976 F.2d 1429, 1434 (D.C. Cir. 1992) (quoting *Renegotiation Bd. v. Grumman Aircraft*, 421 U.S. 168, 184 (1975)).

Plaintiff does not dispute that its FOIA request explicitly sought a “draft” document, and Plaintiff does not challenge in its Opposition the existence of abundant case law holding that “drafts” are generally considered to be predecisional. *See Nat’l Sec. Archive v. CIA*, 752 F.3d 460, 463 (D.C. Cir. 2014) (holding even if the draft never evolves into a final version or decision, “the draft is still a draft and thus still pre-decisional and deliberative”); *Coastal States Gas Corp. v. Dep’t of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980) (“The exemption thus covers . . . draft documents[.]”); *Pies v. IRS*, 668 F.2d 1350, 1353-54 (D.C. Cir. 1981) (holding draft proposed regulations and a draft transmittal memorandum relating to that regulation were exempt as they “were never subjected to final review, never approved by the officials having authority to do so”);

Exxon Corp. v. Dep't of Energy, 585 F. Supp. 690, 698 (D.D.C. 1983) (“Draft documents, by their very nature, are typically predecisional and deliberative.”).

Similarly, Plaintiff does not truly question the Withheld Draft Assessment’s placement in the “temporal sequence” of decisions. The Withheld Draft Assessment reflects an early step in the process leading to a final IRIS Formaldehyde Assessment. Orme-Zavaleta Decl. ¶¶ 8-9. Plaintiff argues that “the relevant decision is not the issuance of the final IRIS Formaldehyde Assessment but the publication of the public review draft at Step 4.” Opp. at 20. Yet, even under Plaintiff’s conception of the “decision” to which the exempted document relates, the Step 1 Withheld Draft Assessment is indisputably predecisional. *See Abtew v. Dep’t of Homeland Sec.*, 808 F.3d 895, 898 (D.C. Cir. 2015) (document is “predecisional if it precedes, in temporal sequence, the decision to which it relates”) (internal quotations and citation omitted).

The Withheld Draft Assessment is also predecisional because it “contribute[s]” to other agency decisions or policies. *Morley v. CIA*, 508 F.3d 1108, 1126-27 (D.C. Cir. 2007) (“the court must first be able to pinpoint an agency decision or policy to which these documents contributed.”) (quoting *Paisley v. CIA*, 712 F.2d 686, 698 (D.C. Cir. 1983), *vacated in part on other grounds*, 724 F.2d 201 (D.C. Cir. 1984)). IRIS assessments contribute to a variety of agency environmental and health recommendations and actions by “inform[ing] the first two steps of the risk assessment process 1) hazard identification and 2) dose-response assessment.” 2d Orme-Zavaleta Decl. ¶ 8 (providing example using other chemical assessment); *see also* Orme-Zavaleta Decl. ¶ 7 (IRIS Assessments “provide the scientific foundation for decision-making to protect public health across EPA”). In the words of one of the GAO reports cited by Plaintiff, “EPA

program offices and regions have increasingly relied on IRIS chemical assessments in making environmental protection and risk management decisions.”⁸

Because the Withheld Draft Assessment is predecisional, Plaintiff pivots to seek the release not of the Withheld Draft Assessment but instead the imagined “Step 4 Formaldehyde Assessment” because it “is not predecisional.” Opp. at 21-22. But as explained above, the only Step 4 assessment is the one released in 2010 and already available on EPA’s website.

Furthermore, Plaintiff misstates Administrator Pruitt’s testimony when it claims there is a “Step 4 Formaldehyde Assessment which was acknowledged by Administrator Pruitt.” *Id.* at 21. Nowhere in the referenced Senate testimony does Administrator Pruitt acknowledge the existence of a draft formaldehyde assessment at Step 4. Simply put, Plaintiff cannot avoid the predecisional nature of the Withheld Draft Assessment by inventing a completed version of the formaldehyde assessment. All of the draft formaldehyde assessments identified in response to Plaintiff’s FOIA request and withheld are versions of Step 1 drafts because the Current Draft Assessment was at Step 1 as a consequence of the agency’s determination to repeat steps of the IRIS assessment process for formaldehyde. 2d Orme-Zavaleta Decl. ¶¶ 6-7. Given the document’s characteristics and status in the agency policymaking process, the Withheld Draft Assessment is “predecisional.”

II. The Withheld Draft Assessment Is Deliberative

EPA also established that that the Withheld Draft Assessment reflects protected deliberative process. *See* Mem. at 7-10. That is, that the Withheld Draft Assessment is “intended

⁸ GAO, GAO-19-270, CHEMICAL ASSESSMENTS: Status of EPA’s Efforts to Produce Assessments and Implement the Toxic Substances Control Act 8, (2019), <https://www.gao.gov/assets/700/697212.pdf>. The GAO report also supports the Orme-Zavaleta Declaration’s statement that work performed on the formaldehyde assessment informs TSCA risk evaluation. *Id.* at 17 n.18 (“TSCA program makes use of some of the information contained in IRIS assessments” even if it doesn’t use IRIS endpoint values); Orme-Zavaleta Decl. ¶ 9.

to facilitate or assist development of the agency’s final position” on a relevant issue. *Nat’l Sec. Archive*, 752 F.3d at 463 (citing *Russell v. Dep’t of Air Force*, 682 F.2d 1045, 1048 (D.C. Cir. 1982)). The deliberative process privilege protects “documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.” *NRLB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150 (1975). The need for protection “rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance ‘the quality of agency decisions,’ by protecting open and frank discussion among those who make them within the Government.” *Dep’t of Interior v. Klamath Water Users Protective Ass’n*, 532 U.S. 1, 8-9 (2001) (citations omitted) (quoting *Sears*, 421 U.S. at 151).

Much of Plaintiff’s attack on EPA’s withholding focuses on the existence of “factual information” contained in the Withheld Draft Assessment. There is no dispute that the Withheld Draft Assessment does contain “factual” material regarding, among other things, the uses, properties, and effects of formaldehyde. But this Circuit has been starkly clear that even purely factual material may be withheld under the deliberative process privilege when “the selection or organization of facts is part of an agency’s deliberative process.” Mem. at 8 (quoting *Ancient Coin Collectors Guild v. Dep’t of State*, 641 F.3d 504, 513-14 (D.C. Cir. 2011)). The settled nature of the law on this is further cemented by the cases raised in Plaintiff’s Opposition.

For example, Plaintiff cites *Mapother v. Department of Justice*, Opp. at 28, wherein the D.C. Circuit held the “great bulk” of a 204-page report prepared for the Attorney General on the wartime activities of Kurt Waldheim as an officer for Nazi Germany was covered by Exemption 5. 3 F.3d 1533, 1535 (D.C. Cir. 1993). Plaintiff’s discussion of the case skips over the salient analysis on which the Court’s holding was based:

Like the information requested in *Montrose Chemical*, the majority of the Waldheim Report's factual material was assembled through an exercise of judgment in extracting pertinent material from a vast number of documents for the benefit of an official called upon to take discretionary action. Therefore, we conclude that the Department properly withheld the product of this process.

Id. at 1539.⁹ The court recognized that the material in the report had a “prominent factual component,” but found the report to be largely exempt because “the selection of the facts thought to be relevant clearly involves ‘the formulation or exercise of ... policy-oriented *judgment*’ and requires ‘exercises of discretion and judgment calls.’” *Id.* at 1538-39 (citations omitted). The only portion of the report that was required to be disclosed was a chronology of Waldheim’s military service (ranks, postings, promotions, decorations, etc.) as it reflected no judgment and “no point of view.” *Id.* at 1539-40.

Plaintiff also discusses *Ancient Coin Collectors Guild*, which concerned reports from the Cultural Property Advisory Committee to the State Department advising on import restrictions. There, the factual information in the federal advisory committee reports was “culled by the Committee from the much larger universe of facts presented to it” and reflects an “exercise of judgment as to what issues are most relevant to the pre-decisional findings and recommendations,” and “the factual summaries therefore reflect [the committee’s] pre-decisional deliberative process.” 641 F.3d 504, 513-14 (D.C. Cir. 2011) (affirming withholding).

⁹ Plaintiff suggests the *Mapother* decision turned on comparing a draft version to a final public version, thereby disclosing what was excluded in the final version. Opp. at 28. Plaintiff argues this distinguishes *Mapother* from the present litigation where there is no final public version. Even a cursory reading of *Mapother* reveals that was not the basis for the court’s holding. Nor was the ruling in *Mapother* grounded on the report being, what Plaintiff terms, a “special-use fact memo” or the nature of the “specific evidence compiled.” *Id.* at 29.

Both *Mapother* and *Ancient Coin Collectors Guild* relied on the D.C. Circuit’s decision in *Montrose Chemical Corp. v. Train*, 491 F.2d 63 (D.C. Cir. 1974).¹⁰ In its Memorandum, EPA compared the holding in *Montrose Chemical* to the facts established in the Orme-Zavaleta Declaration. Mem. at 9. In *Montrose Chemical*, the court explained how distilling public testimony and evidence—of separating the significant facts from the insignificant facts—to facilitate the EPA Administrator’s decision on DDT registrations constituted protected deliberative process. *Montrose Chem.*, 491 F.2d at 68 (EPA personnel “were exercising their judgment as to what record evidence would be important” . . . “making an evaluation of the relative significance of the facts recited” . . . “separating the pertinent from the impertinent is a judgmental process”). Dr. Orme-Zavaleta testified that the Withheld Draft Assessment reflects the “selection, organization, and analysis of factual information” regarding formaldehyde and such work “constitutes an exercise of judgment by EPA staff.” Orme-Zavaleta Decl. ¶ 15. More specifically, the Withheld Draft Assessment reflects “identification of relevant studies across multiple scientific disciplines . . . evaluation of study methods; analysis and synthesis of evidence from identified studies . . . and hazard identification.” *Id.* Even though the subject matters differ, this is the same type of deliberative process identified in *Montrose*, *Mapother*, and *Ancient Coin Collectors Guild*. “Exemption 5 was intended to protect not simply deliberative material, but also the deliberative process of agencies.” *Montrose Chem.*, 491 F.2d at 71.

Furthermore, EPA demonstrated how “draft” documents that would lead or contribute to a final agency decision, policy, or position are often considered to be deliberative. Mem. at 8. In response, Plaintiff misrepresents EPA’s argument as “essentially that any materials not approved

¹⁰ Plaintiff’s Opposition states that this case “is cited by EPA for the proposition that drafts are inherently deliberative,” Opp. at 34, which is a misrepresentation of EPA’s Memorandum.

for public release are deliberative.” Opp. at 31. Rather, EPA’s argument is that “draft” documents, by their nature, possess the hallmarks of deliberative process.¹¹

Plaintiff then makes the counterfactual assertion that the Current Draft Assessment includes a “Step 4 version” or “ready for public release” document and therefore is not really a draft or reflect preliminary agency position.¹² Opp. at 32-34. Plaintiff demands production of the “‘clean’ or Step 4 version of the Formaldehyde Report described by Administrator Wheeler.” Opp. at 31. EPA assumes Plaintiff meant Administrator Pruitt because it has not cited to any particular statement from Administrator Wheeler. Administrator Pruitt did not describe or reference a “clean” or “Step 4” version of the Current Assessment (in contrast to 2010 Assessment that did reach Step 4). Plaintiff’s pivot to seek some hypothetical other document—which again does not exist—illustrates the difficulty Plaintiff has in contending that the Withheld Draft Assessment is not protected deliberative process. The record reflects that it is a redlined, draft report (i.e., not yet subject to intra- or inter-agency review) reflecting the preliminary “exercise of judgment by EPA staff” regarding the “type of analysis EPA should be conducting, which scientific studies

¹¹ See, e.g., *Shurtleff v. EPA*, Civ. A. No. 10-2030 (EGS), 2012 WL 4472157, at *17 (D.D.C. Sept. 25, 2012) (recommending exemption of drafts of “Endangerment Finding” (regarding the effect of six greenhouse gasses) because disclosure would reveal the agency’s deliberative process in developing the Endangerment Finding); *Goodrich Corp. v. EPA*, 593 F. Supp. 2d 184, 189 (D.D.C. 2009) (holding draft of groundwater flow model exempt as it reflects EPA’s deliberative process because, quoting the agency declaration, “evolving iterations of the Model’s inputs and calibration reflect the opinions of the staff currently developing the Model, which may not represent EPA’s ultimate opinions relating to these matters”); *TecheServe All. v. Napolitano*, 803 F. Supp. 2d 16, 27-28 (D.D.C. 2011) (holding draft of inspector general review, which was modified prior to final release, to be exempt).

¹² Plaintiff cites *Heartwood, Inc. v. U.S. Forest Service* for the position that a draft must reflect an agency’s “preliminary positions or ruminations” relating to a policy to qualify as deliberative. Opp. at 32. But there, “the drafts consist[ed] only of factual narratives and summaries provided by a non-agency group to the USFS of material already available to the public, the release of [which] will not chill the ‘frank and honest communication within the agency.’” 431 F. Supp. 2d 28, 38 (D.D.C. 2006).

should be used as part of the assessment, and the type, scope, and substantive content of the agency's proposed conclusions and recommendations." Orme-Zavaleta Decl. ¶¶ 14-15. The Withheld Draft Assessment is part of EPA's deliberative process that will yield a final position on formaldehyde toxicity and inform "other actions or . . . recommendations to manage environmental and health risks" relating to formaldehyde. 2d Orme-Zavaleta Decl. ¶ 8.

Finally, Plaintiff cannot avoid the Withheld Draft Assessment's exemption by arguing that "the sanctity of the claimed deliberative process . . . has already been disturbed by EPA's ongoing willingness to make selective disclosures to industry." Opp. at 23. Specifically, Plaintiff asserts that at a January 24, 2018, meeting between EPA and the ACC Panel, EPA effectively disclosed the contents of the Current Draft Assessment, causing it to "los[e] its status as an 'intra-agency' document. *Id.* First, IRIS Program personnel "has frequently met with members of the public to hear stakeholder perspectives." 2d Orme-Zavaleta Decl. ¶ 9. Second, with respect to the January 24, 2018 meeting with the ACC Panel, Dr. Orme-Zavaleta participated in that meeting, and she confirms that EPA did not share copies of the Current Draft Assessment or portions of the draft.¹³ Plaintiff has not met its burden to show that the agency has waived the deliberative process privilege through disclosure. *Assassination Archives & Research Ctr. v. CIA*, 334 F.3d 55, 60 (D.C. Cir. 2003).

¹³ Having a meeting with an outside group about the subject of the formaldehyde assessment does not "waive" the deliberative process protection for an intra-agency document. Plaintiff's reliance on *Klamath* is unavailing. That case concerned application of the "consultant corollary," which pertains to situations in which outside consultants have effectively functioned as agency employees thereby obtaining the deliberative process protections. Specifically, the Supreme Court held in *Klamath* that certain records submitted to the agency by Indian tribes did not fall within Exemption 5. 532 U.S. at 16. That is not the situation here.

III. Foreseeable Harm Would Result From Disclosure

Plaintiff raises the FOIA Improvement Act's codification of a "foreseeable harm" standard whereby an agency shall withhold information only if "(I) the agency reasonably foresees that disclosure would harm an interest protected by an exemption described in subsection (b); or (II) disclosure is prohibited by law." 5 U.S.C. § 552(a)(8)(A)(i).

In its Memorandum, EPA presented and explained two specific foreseeable harms that could result from disclosure of the Withheld Draft Assessment: it would discourage candid analysis and create public confusion. Plaintiff asks the Court to disregard EPA's proffered harms as "boilerplate," *Opp.* at 38, but Plaintiffs ignore the specificity provided by the agency. EPA explained that disclosure of the Withheld Draft Assessment "would discourage candid evaluations and discussions in future draft assessments of chemicals." Orme-Zavaleta Decl. ¶ 17. The D.C. Circuit has recognized that "release of drafts that never result in final agency action," as is the case with the formaldehyde assessment, "would discourage innovative and candid internal proposals by agency officials and thereby contravene the purposes of the [deliberative process] privilege." *Nat'l Sec. Archive*, 752 F.3d at 463; *see also Reliant Energy Power Generation, Inc. v. FERC*, 520 F. Supp. 2d 194, 204 (D.D.C. 2007) (holding that disclosure of draft staff report investigating alleged abuses of energy market would have "chilling effect on communication between agency employees regarding similar projects and (sic) the future").

EPA did not simply assert a potential chilling effect on frank analyses and evaluations; it explained how that foreseeable harm would manifest itself. The Formaldehyde Assessment is intended to provide EPA's position on the human health hazards of formaldehyde. Orme-Zavaleta Decl. ¶¶ 7, 15. EPA is currently working on 15 other assessments of chemicals under the IRIS program. *Id.* ¶ 7. "If the staff working on this Assessment or a similar Assessment knew that all of their edits and comments would someday be released to the public, they would be less likely to

freely discuss how EPA should be doing scientific analysis, which studies are the most relevant in any particular context, and what conclusions the agency should draw.” *Id.* ¶ 17. This would then “harm the agency’s decision-making capabilities” for agency evaluations of formaldehyde and other policymaking. *Id.* “The privilege protects ‘debate and candid consideration of alternatives within an agency,’ thus improving agency decision-making.” *Machado Amadis v. U.S. Dep’t of State*, Civ. A. No. 19-5088, 2020 WL 4914093, at *4 (D.C. Cir. Aug. 21, 2020) (quoting *Jordan v. DOJ*, 591 F.2d 753, 772 (D.C. Cir. 1978) (en banc)).

Plaintiff does not disagree with the proposition that the premature release of draft assessments could have a chilling effect on the candor of EPA’s scientific staff. Instead, Plaintiff argues that the concern is “absent in this case” because the “Formaldehyde Assessment was completed in all but name” and “internal deliberations are not revealed in this final product.” *Opp.* at 39. Except that the Current Draft Assessment was not “complete” or a “final product,” as stated in the Second Orme-Zavaleta Declaration (¶¶ 3, 6-7). Plaintiff’s reliance on a counterfactual belief cannot undermine the proffered harm that would result from the premature disclosure of a draft redlined assessment of the health effects of formaldehyde. Courts accord agency declarations “a presumption of good faith, which cannot be rebutted by purely speculative claims about the existence and discoverability of other documents.” *SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991) (quotation marks omitted).

Plaintiff further argues that, because “scientists already expect to have their scientific judgments closely examined” through peer review, there is “no showing of how agency staff might be less candid in other scientific assessments.” *Opp.* at 30. This unsupported assertion conveniently ignores the fact that scientists submit *final* versions for peer review, not redlined drafts like the Withheld Draft Assessment.

With respect to the second foreseeable harm, EPA did not simply assert that releasing the Withheld Draft Assessment “would cause public confusion.” It explained how it could cause confusion in multiple ways. It would disclose “particular positions that may not represent the agency’s decisionmakers’ final conclusions on the health effects of formaldehyde.” Orme-Zavaleta Decl. ¶ 18. It would “reveal[] staff opinions, which may or may not ripen into the final conclusions” of the agency. *Id.* Again, the Withheld Draft Assessment had not been subject to the intra-agency and inter-agency reviews (Steps 2 and 3), which could result in material changes to the assessment. *Id.* ¶ 14. Furthermore, the “release of a document with numerous red-lined edits may confuse the public as to what conclusions the document actually draws.” *Id.* ¶ 18.

Plaintiff responds that further confusion is “inconceivable” because the public is “already terminally confused.” *Opp.* at 39. Plaintiff did not cite case law for this novel argument, but Plaintiff also misses the point. Plaintiff argues that there is already confusion about the *status* of the formaldehyde study, *id.* (public “confused about why . . . Assessment was abandoned”), which is unrelated to and does not detract from the harm anticipated by EPA from a premature disclosure of a draft chemical assessment. Plaintiff also argues that perhaps EPA “by marking the document as a draft,” like EPA did with the publicly released 2010 Formaldehyde Draft, could “easily resolve[]” confusion. *Opp.* at 39-40. Plaintiff’s proposal would increase, not resolve confusion, by equating a document EPA specifically released for public comment with a document that EPA did not release for public consumption.

This is precisely why deliberative documents are exempt. As stated by the D.C. Circuit, “[d]ocuments which are protected by the privilege are those which would inaccurately reflect or prematurely disclose the views of the agency, suggesting as agency position that which is as yet only a personal position.” *Coastal States*, 617 F.2d at 866. Courts discourage disclosing

unadopted drafts since “such documents, if released, may actually mislead the public as to the policy of the agency.” *Pies*, 668 F.2d at 1353.

In sum, EPA has articulated specific foreseeable harms to exemption protected interests and explained the how those harms would occur through the premature disclosure of the Withheld Draft Assessment. Plaintiff’s characterization as “empty boilerplate” rings hollow.

IV. The Withheld Draft Assessment Is Not Segregable

It appears that Plaintiff is attempting to modify its FOIA request, which had sought the entire draft formaldehyde assessment. Orme-Zavaleta Decl. ¶ 6, Exhibit A. Now, Plaintiff insists on partial disclosure of any portion of the draft that contains “purely factual information.” Opp. at 40-41.¹⁴ The D.C. Circuit has found that it is appropriate to withhold the entire draft where the FOIA requester “asked not for particular factual material, but for the draft” document. *Nat’l Sec. Archive*, 752 F.3d at 463; *see also Hamilton Sec. Grp. Inc. v. HUD*, 106 F. Supp. 2d 23, 33 (D.D.C. 2000) (finding requested “copy of the draft [audit] report” was not reasonably segregable).

Despite this legal precedent involving analogous situations of requests for entire draft documents, EPA did consider whether any portion of the Withheld Draft Assessment is segregable. Orme-Zavaleta Decl. ¶ 16; Bell Decl., Ex 3 at 2. EPA concluded that the Withheld Draft Assessment is not segregable because the factual content is “so thoroughly integrated with agency deliberations” regarding that content. Orme-Zavaleta Decl. ¶ 16. EPA does not need to disclose

¹⁴ Elsewhere in its Opposition, Plaintiff argues that “there is no reason to withhold factual information previously released in the 2010 Formaldehyde Draft.” Opp. at 26. For one, releasing it would not be necessary because that information is already public. For another, putting aside the EPA found the draft to be not reasonably segregable, and assuming such information exists, parsing the draft to release information appearing in the 2010 Assessment invades the protected interests of the deliberative process privilege. It would “reveal which facts [from the 2010 Assessment] the agency decided to include or exclude” thereby revealing a portion of its deliberative process. *See* Opp. at 28 (citing case law holding that invasion is inappropriate).

“non-exempt portions . . . inextricably intertwined with exempt portions.” *Mead Data Cent., Inc. v. Dep’t of Air Force*, 566 F.2d 242, 260 (D.C. Cir. 1977). EPA further explained why the Withheld Draft Assessment is not segregable:

Withheld Draft Assessment synthesizes and integrates evidence from multiple scientific lines of information (human, animal, and mechanistic studies) to develop conclusions. Integration of evidence across studies inherently requires scientific judgment and consideration of the strengths and weaknesses of the available studies. Thus, the disclosure of even the factual information contained within the Withheld Draft Assessment would expose the agency’s deliberative process, including exposing the agency’s preliminary deliberations, thoughts, and analyses.

Orme-Zavaleta Decl. ¶ 16. Thus, Plaintiff’s assertion that EPA “made no attempt to segregate . . . or to specify why it could not,” Opp. at 41, is easily refuted.¹⁵

The existence of redlined edits and comments further supports a finding that any supposedly exempt and non-exempt material are intertwined. *See Ctr. for Biological Diversity v. EPA*, 369 F. Supp. 3d 1, 26 (D.D.C. 2019) (holding non-segregability of draft Addenda and “draft response to comments” document where agency declared that any potentially non-exempt material was “interspersed throughout the documents, often with extensive edits, making them inextricably intertwined with privileged information”). Plaintiff does not address, and therefore concedes, EPA’s position that any purportedly factual, non-exempt material is inextricably intertwined with indisputably exempt information. Mem. at 11-12.

¹⁵ Plaintiff admits that EPA is entitled to a presumption of compliance with its obligation to attempt to segregate non-exempt material. Opp. at 41; *see Hodge v. FBI*, 703 F.3d 575, 582 (D.C. Cir. 2013).

CONCLUSION

For the foregoing reasons, EPA respectfully requests that the Court grant summary judgment in its favor and deny Plaintiff's cross-motion for summary judgment.

Dated: September 3, 2020

Respectfully submitted,

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