UNITED STATES DISTRICT COURT DISTRICT OF OREGON PORTLAND DIVISION

NORTHWEST ENVIRONMENTAL ADVOCATES, an Oregon nonprofit corporation,

Case No. 3:15-cv-01151-HZ

Plaintiff,

UNOPPOSED MOTION TO MODIFY CONSENT DECREE

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY and SCOTT PRUITT, in his official capacity as Administrator of the United States Environmental Protection Agency,

Defendants.

Defendants United States Environmental Protection Agency and Scott Pruitt, in his official capacity as Administrator of the United States Environmental Protection Agency, (collectively, "EPA") hereby move the Court, pursuant to Federal Rule of Civil Procedure 60(b), for an order modifying the Consent Decree, ECF No. 20, entered by this Court on June 7, 2016, to extend the deadlines regarding the human health arsenic criteria set forth in Paragraphs 5 and 6 of the Consent Decree. In support of its Motion, EPA avers as follows:

1. Prior to filing this Motion, EPA conferred with Plaintiff Northwest Environmental Advocates ("NWEA"). Based on those communications and the representations EPA proffers herein, and without waiving any of their rights under the Consent Decree, NWEA consents to EPA's filing this Motion and agrees with EPA that there is good cause for the requested Consent

¹ Scott Pruitt is substituted for Gina McCarthy pursuant to Fed R. Civ. P. 25(d).

Decree modification, that it is both necessary and justified under Rule 60(b), and that it is in the public's interest.

2. Paragraph 5 of the Consent Decree provides:

If EPA's action is to disapprove Idaho's 2010 [human health arsenic criteria] submission, and Idaho does not adopt replacement criteria that EPA approves by November 15, 2018, EPA shall sign for publication in the Federal Register a proposed regulation setting forth new human health arsenic criteria for Idaho by November 15, 2018.

3. Paragraph 6 of the Consent Decree provides:

If EPA signs proposed new arsenic criteria for Idaho by November 15, 2018, and Idaho does not adopt replacement criteria that EPA approves by July 15, 2019, EPA will sign a notice of final rulemaking action on EPA's proposed arsenic criteria for Idaho by July 15, 2019.

- 4. As set forth in the Consent Decree, EPA expects to update its *Integrated Risk Information System ("IRIS") Toxicological Review of Inorganic Arsenic*. Consent Decree ¶ 4.

 The last time the Agency revised the *IRIS Toxicological Review of Inorganic Arsenic* was in

 June 1995.²
- 5. At the time the Consent Decree was entered, EPA was in the process of updating the *IRIS Toxicological Review of Inorganic Arsenic* and anticipated finalizing and posting it to the IRIS database in 2017. EPA has always intended to finalize the *IRIS Toxicological Review of Inorganic Arsenic* before proposing Idaho arsenic criteria (as necessary), and to use the *IRIS Toxicological Review of Inorganic Arsenic* as an important part of the basis for those proposed

² EPA's IRIS Program is intended to provide high quality, publicly available information on the toxicity of chemicals to which the public might be exposed. IRIS assessments are not regulations, but they provide a critical part of the scientific foundation for decision-making to protect human health across EPA under an array of environmental laws, including the Clean Water Act.

criteria. As explained further below, however, EPA now anticipates it will post a final *IRIS Toxicological Review of Inorganic Arsenic* no earlier than summer 2021.

- 6. In 2011, the National Academy of Sciences ("NAS") recommended that EPA employ "systematic review" in developing its toxicity evaluations.³ The goal of systematic review is to ensure that the review is complete, unbiased, reproducible, and transparent. Prior to 2011, systematic review was not routinely used in the field of environmental health. The NAS recommendations were echoed by certain stakeholders and further amplified by congressional requests.
- 7. In a 2014 follow-up report,⁴ the NAS found that EPA had made progress in acting on the 2011 recommendations, but also recognized that NAS' suggested changes would take several years and extensive EPA effort to implement. EPA's efforts to implement systematic review for the IRIS Program and respond to congressional requests are described in EPA's January 2018 Report to Congress.⁵
- 8. In January 2017, EPA hired a systematic review expert as a new career-level Director for its IRIS Division. Given the importance of the *IRIS Toxicological Review of Inorganic Arsenic* and EPA's plan to request the NAS to peer review it, it became evident that, despite being somewhat advanced in the development process, the existing draft arsenic assessment should be recast to fulfill the NAS recommendations. This additional effort would

³ Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Available at http://www.nap.edu/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-offormaldehyde.

⁴ Review of EPA's Integrated Risk Information System (IRIS) Process. Available at http://www.nap.edu/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process.

⁵ EPA's Integrated Risk Information System (IRIS) Program Report to Congress. Available at https://www.epa.gov/sites/production/files/2018-02/documents/iris_report_to_congress_2018.pdf.

lead to standardized and transparent evaluation of the strengths and weaknesses of critical studies, a strengthened and more integrative weight-of-evidence evaluation, and clearer rationale for selecting the studies advanced for consideration in calculating toxicity values. EPA expects to present a draft systematic review protocol of the *IRIS Toxicological Review of Inorganic Arsenic* that describes these changes to the NAS for review in fall 2018.

- 9. EPA's Office of Research and Development anticipates that it will produce an external review draft *IRIS Toxicological Review of Inorganic Arsenic* (for peer review) in winter 2020 and a final *IRIS Toxicological Review of Inorganic Arsenic* during summer 2021. Once this process is complete, EPA and the public will benefit from having the final peer-reviewed assessment, and the science supporting that assessment, as part of the supporting record for the proposed Idaho arsenic criteria.
- proposing arsenic criteria for Idaho would allow for efficient and effective use of federal resources and, most importantly, would ensure that EPA's proposal is based on a fully developed record that incorporates up-to-date science and has withstood the most rigorous review.

 Additionally, delaying EPA's proposal of Idaho arsenic criteria would have two additional benefits: the public would be less likely to need to engage in multiple administrative review processes, and it will ensure that any proposed criteria would benefit from information in the revised *IRIS Toxicological Review of Inorganic Arsenic*.
- 11. The Consent Decree provides for modification by the Court upon a showing of good cause. *See* Consent Decree ¶ 12. Similarly, Federal Rule of Civil Procedure 60(b) authorizes courts to modify any final judgement or order in cases where "applying it

prospectively is no longer equitable" or for "any other reason that justifies relief." Fed. R. Civ. P. 60(b)(5), (6).

- 12. As long recognized by the Supreme Court, "sound judicial discretion may call for the modification of the terms of an injunctive decree if the circumstances, whether of law or fact, obtaining at the time of its issuance have changed, or new ones have since arisen." *System Federation No. 91, Railway Employees' Department, AFL-CIO v. Wright*, 364 U.S. 642, 647 (1961). Where the moving party demonstrates a change of law or fact warranting modification of the consent decree, the court "should consider whether the proposed modification is suitably tailored to the changed circumstance." *Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 383 (1992).
- 13. In light of the foregoing unexpected developments and expectations, which might result in new information that could inform appropriate human health arsenic criteria for Idaho, it would be in the public interest to modify and extend the deadlines established by Paragraphs 5 and 6 of the Consent Decree. Specifically, EPA requests that this Court modify and extend the deadline for signing for publication in the Federal Register a proposed regulation setting forth new human health arsenic criteria in Idaho from November 15, 2018, to November 15, 2022. See Consent Decree ¶ 5. In addition, EPA requests that this Court modify and extend the deadline for signing a notice of final rulemaking action on EPA's proposed human health arsenic criteria in Idaho from July 15, 2019, to November 15, 2023. See id. ¶ 6.

CONCLUSION

Accordingly, EPA respectfully requests that the Court enter an order modifying the Consent Decree by extending the Paragraph 5 deadlines to November 15, 2022, and the Paragraph 6 deadlines to November 15, 2023.

Respectfully submitted,

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Dated: June 12, 2018

CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2018, I served the foregoing United States' Unopposed Motion to Modify Consent Decree on the following counsel for Plaintiffs via ECF:

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