

May 18, 2026

**VIA REGULATIONS.GOV DOCKET ID: ATSDR-2026-0001**

Agency for Toxic Substances and Disease Registry (ATSDR)  
Office of Innovation and Analytics  
4770 Buford Highway  
Mail Stop S106-5  
Atlanta, GA, 30341-3717  
Attn: Docket No. ATSDR-2026-0001  
<https://www.regulations.gov/search?filter=ATSDR-2026-0001>

Re: *Nominations for Substances to be Evaluated for Toxicological Profile Development*

**I. INTRODUCTION AND SUMMARY OF NOMINATIONS**

We submit this comment on behalf of Informed Consent Action Network (“ICAN”) in response to the Agency for Toxic Substances and Disease Registry’s (“ATSDR”) notice published in the Federal Register on March 17, 2026, soliciting public nominations of substances to be evaluated for toxicological profile development pursuant to Section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.<sup>1</sup> We respectfully nominate the following four substances for evaluation and development of new or updated toxicological profiles, **with particular attention to their injection directly into the body**, as used in vaccines administered to the general population, including infants, children, and pregnant women:

1. Aluminum (CAS No. 7429-90-5)
2. Mercury (CAS No. 7439-97-6)
3. Phenol (CAS No. 108-95-2)
4. Formaldehyde (CAS No. 50-00-0)

Each of these substances appears on ATSDR’s Substance Priority List, confirming that ATSDR and the US Environmental Protection Agency have already determined that they pose a significant threat to human health due to their known or suspected toxicity and potential for human exposure.

ICAN has a particular interest in the development of these toxicological profiles given its focus on and work concerning informed consent. Comprehensive, authoritative toxicological data is essential to ensuring that healthcare providers can fulfill their legal and ethical obligations to disclose material information about vaccine ingredients and risks, and that patients and parents can

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<sup>1</sup> Federal Register, Nominations for Substances to be Evaluated for Toxicological Profile Development, (Mar. 17, 2026), <https://www.federalregister.gov/documents/2026/03/17/2026-05164/nominations-for-substances-to-be-evaluated-for-toxicological-profile-development>.

make meaningful, informed decisions regarding medical interventions administered to themselves and their children.

## II. BASIS FOR NOMINATIONS

### A. Presence on the ATSDR Substance Priority List

The ATSDR 2025 Substance Priority List ranks the nominated substances as follows: Aluminum at 95, Mercury at 23, Phenol at 104, and Formaldehyde at 276.<sup>2</sup>

### B. Use of Nominated Substances in Vaccines

These substances are present in numerous vaccines currently licensed for use in the United States and administered routinely to infants, children, adolescents, and adults, including pregnant women. Their roles in vaccine formulations include:

**Aluminum:** used as an adjuvant<sup>3</sup> in the form of aluminum salts (i.e., aluminum hydroxide, aluminum phosphate) to help stimulate an immune response. Aluminum and/or aluminum-containing adjuvants are present in vaccines for DTaP, Tdap, hepatitis A, hepatitis B, *Haemophilus influenzae* type B (Hib), human papillomavirus (HPV), pneumococcal disease, meningococcal disease, and others.<sup>4</sup>

**Mercury:** in the form of the mercury-containing compound, thimerosal, is used as a preservative<sup>5</sup> in some multi-dose vaccine vials and can also be present as a manufacturing residue. Thimerosal can be found in some multi-dose influenza vaccine preparations and in one tetanus-diphtheria vaccine.<sup>6</sup>

**Phenol:** is used as an inactivating agent or preservative in certain vaccines including pneumococcal disease and Hib.<sup>7</sup>

**Formaldehyde:** used during the manufacturing process as an inactivating ingredient<sup>8</sup> to weaken or kill viruses or to inactivate toxins. It is present as a residual in numerous vaccines, including vaccines for diphtheria-tetanus-pertussis (DTaP, Tdap), hepatitis A, hepatitis B, influenza, meningococcal disease, and others.<sup>9</sup>

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<sup>2</sup> ATSDR, 2025 Full SPL Spreadsheet, <https://www.atsdr.cdc.gov/programs/substance-priority-list.html>.

<sup>3</sup> U.S. Dep't of Health & Hum. Servs., *Vaccine Ingredients*, HHS.gov, <https://www.hhs.gov/immunization/basics/vaccine-ingredients/index.html>.

<sup>4</sup> Inst. for Vaccine Safety, Johns Hopkins Bloomberg Sch. of Pub. Health, *Excipients in Routinely Recommended Vaccines*, <https://www.vaccinesafety.edu/components-excipients/>.

<sup>5</sup> See, supra note 3.

<sup>6</sup> See, supra note 4.

<sup>7</sup> *Id.*

<sup>8</sup> See, supra note 3.

<sup>9</sup> See, supra note 4.

### **C. Significance of Exposure Through Vaccination**

The route of exposure for these substances in the vaccine context is intramuscular or subcutaneous injection, which bypasses the body's normal protective barriers such as the gastrointestinal tract, skin, and respiratory epithelium. Vaccines are administered to virtually the entire US population under the CDC recommended immunization schedule, beginning at birth and continuing throughout the lifespan.<sup>10</sup> Vulnerable populations—including neonates, infants, young children, and pregnant women—often receive multiple vaccinations on a single day.

Existing ATSDR toxicological profiles for these substances have focused primarily on environmental exposure pathways such as inhalation, ingestion of contaminated food and water, and dermal contact. Thus, there is a need for comprehensive toxicological evaluation that addresses the specific exposure scenario presented by injection of these substances at the doses and frequencies found in routine immunization schedules, particularly in susceptible subpopulations such as pregnant women, infants, and developing children.

### **D. Public Health Justification**

ATSDR toxicological profiles are treated nationally and internationally as credible sources of information for public health professionals. Each peer-reviewed profile identifies and reviews the key literature that describes a substance's toxicological properties, including health and toxicological information on the potential for human exposure, chemical and physical properties, and regulations and guidelines. Development or updating of toxicological profiles for the nominated substances would serve important public health objectives, including:

1. Providing a comprehensive, peer-reviewed synthesis of available scientific literature on the toxicity of these substances via injection exposure at doses relevant to vaccination;
2. Establishing or updating minimal risk levels that account for the injection route and particular vulnerabilities of infants and children;
3. Identifying data needs and gaps in existing scientific literature regarding the health effects of these substances when administered via injection; and
4. Supporting informed decision-making by public health professionals, policymakers, and the public regarding the safety of vaccine excipients.

## **III. SUPPORTING LITERATURE**

A list of supporting literature is attached as Schedule "A."

## **IV. CONCLUSION**

For the foregoing reasons, we respectfully request that ATSDR prioritize comprehensive updating of the toxicological profiles for aluminum, mercury, phenol, and formaldehyde, with

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<sup>10</sup> Ctrs. for Disease Control & Prevention, Vaccines & Immunizations, *Healthcare Professionals: Immunization Schedules*, (Jul. 2, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/index.html>.

specific attention to their toxicological properties when administered via injection in the quantities and schedules associated with routine vaccination.

These substances are already recognized as posing significant threats to human health, as evidenced by their placement on the ATSDR's Substance Priority List. The widespread exposure of the general population to these substances through vaccination—particularly among infants and children—underscores the importance of comprehensive toxicological evaluation that addresses this unique route and context of exposure.

We appreciate ATSDR's consideration of these nominations and its commitment to protecting public health through the development of toxicological information.

Very truly yours,



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## Schedule A

Angrand L. et al., *Regulatory Limits of Aluminum Content of Vaccines Have Not Been Set Based on Toxicological Studies*, 119 *Envtl. Toxicol. & Pharmacol.* 104812 (2025), <https://doi.org/10.1016/j.etap.2025.104812>.

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