

Waiver Notice

On December 23, 2024, pursuant to section 319 of the Public Health Service (PHS) Act, Health and Human Services (HHS) Secretary Becerra determined that, as a result of the consequences exposure risk from H5N1 in improperly pasteurized milk throughout the United States this constitutes the conditions in which a disease or disorder is significantly likely to become a public health emergency (SLPHE).

The Secretary's determination to declare the SLPHE was made after consulting with public health officials as necessary. As a result of the SLPHE, the Secretary also determined pursuant to section 319(f) of the PHS Act that the circumstances of the SLPHE necessitate a waiver from the requirements of the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., effective as of the date of this notice. The waiver is justified to collect information to support the Department's data collection on milk pasteurization failure resulting in intrastate product recall. This waiver applies to information to be collected by the Food and Drug Administration (FDA) related to H5N1 exposure risk in improperly pasteurized milk.

Pursuant to the waiver, the requirements of 44 U.S.C. § 3501 et seq. shall not be applicable with respect to the voluntary collection of information related to the H5N1 exposure risk in improperly pasteurized milk during the effective time period.

The Paperwork Reduction Act waiver is effective as of January 14, 2025, and is anticipated to remain in effect throughout the time period of the immediate investigation of and response to the disease or disorder significantly likely to become a public health emergency pursuant to section 319(a) of the PHS Act, and for a reasonable length of time for immediate post response review regarding the disease or disorder Significantly likely to become a public health emergency.

Any initiative subject to this waiver that is ongoing after the termination of the effective period shall be subject to the requirements of the Paperwork Reduction Act within 60 days of expiration of the waiver. The waiver applies to the Food and Drug Administration.

This notice will be updated as needed.