

ICR Non-Substantive CHANGE REQUEST MEMO

ICR Title: [NCIRD] National Disease Surveillance Program - II. Disease Summaries

OMB NO. 0920-0004

Expiration Date 4/30/2026

Summary:

Edits to three novel influenza A data collection instrument are necessary to add questions on unpasteurized milk/milk products and cattle/cattle farms exposures.

In the detailed case report form (attachment K), we have defined "Direct Contact", and replaced term "close contact" with "other contact" and we have added 19 questions related to milk/milk products and livestock exposure. These new questions will only be asked of individuals who were infected with an avian influenza A virus, and who also indicated they had been exposed to animals.

In the screening form (attachment P), we have expanded from asking only about bird and swine exposure to asking about other animal exposures.

In the aggregate monitoring form (attachment EE), we have changed the categories of exposure from employee type (e.g., federal responder, state responder, etc.) to setting type (e.g., commercial poultry farm, commercial cattle farm, etc.). We have also modified the footnotes to clarify who should be counted in the table.

These edits are minimal and will not change the overall scope of the package. The minimal change in estimated burden is only needed so that CDC can collect the needed data that is associated with the HPAI (A) H5N1 response.

Attachments:

- 1) Attachment K: Human Infection with Novel Influenza A Virus Case Report Form
- 2) Attachment P: Novel Influenza A Virus Case Screening Form
- 3) Attachment EE: Aggregate counts of persons exposed to Highly Pathogenic avian influenza (HPAI)

Background & Justification:

In spring of 2024, highly pathogenic influenza (HPAI) A (H5N1) virus was detected in dairy cattle. Soon after the detections in dairy cattle, a human case who was exposed to dairy cattle was identified. The current novel influenza A data collection forms do not collect information to ascertain exposures to unpasteurized milk/milk products or exposures to cattle or cattle farms. Until 2024, these were not known risks.

Proposed changes to this project will result in improved understanding of the risk of milk/milk products and cattle/cattle farms and HPAI virus infection.

Effect of Proposed Changes on Current Approved Instruments:

Form	Current/Question Item	Requested Change
Attachment K: Human Infection with Novel Influenza A Virus	Type of influenza vaccine (check all that apply): Inactivated (injection) Live attenuated (nasal spray)	Type of influenza vaccine (check all that apply): Inactivated (injection) Live attenuated (nasal spray)

ICR Non-Substantive CHANGE REQUEST MEMO

Case Report Form	Unknown	Other _____ Unknown
	56. In the 10 days before becoming ill, did the patient attend an agricultural fair/ or event?	56. In the 10 days before becoming ill, did the patient attend an agricultural fair/ or event? (e.g. show or auction)?
	59. In the 10 days before becoming ill, did the patient have DIRECT contact with (e.g., touch or handle) any animals?	59. In the 10 days before becoming ill, did the patient have direct contact with any animals? Direct contact is defined as: handling, touching, or petting an animal. This could have been at your home or another home, at a pet store, petting zoo, retail store, school, daycare, or other location.
	61. Where did the direct contact occur (check all that apply)? Home Work Agricultural fair or event Live animal market Petting zoo Other _____	61. Where did the direct contact occur (check all that apply)? Home Work Agricultural fair or event Live animal market Petting zoo Slaughterhouse/rendering facility Other _____
	62. In the 10 days before becoming ill, did the patient have CLOSE contact with (e.g., walk through an area containing or come within about 6 feet of) any animals?	62. In the 10 days before becoming ill, did the patient have any other exposure to (touch potentially contaminated surfaces, walk through an area containing or come within about 6 feet of) any animals?
	63. What type(s) of animals did the patient have close contact with (check all that apply)?	63. What type(s) of animals did the patient have this exposure to from Q.62 (e.g. touch potentially contaminated surfaces, walk through an area containing or come within 6 feet of) (check all that apply)?
	64. Where did the close contact occur (check all that apply)?	64. Where did this exposure occur (check all that apply)?
		66. In the 10 days before becoming ill, did the patient have direct or any other contact with any animal confirmed to be influenza A positive? Yes (specify animal type and location) (specify influenza subtype (if known)) No Unknown
		69. In the 10 days before becoming ill, did the patient drink any raw or unpasteurized milk from a cow or other animal sources, including drinking milk on the farm where it was

ICR Non-Substantive CHANGE REQUEST MEMO

		produced or drinking milk from the “bulk tank”? Yes No Unknown Refused (If yes ask sub-questions a through g, write in “Refused” if refused to answer or “NA” if question not applicable) a) What type of milk (cow milk, goat milk, etc.), variety, and brand: _____ Unknown b) What was the first date of consumption in the 10 days before becoming ill (MM-DD-YYY): _____ Unknown c) Where was the milk acquired (store name, farm name, herd share, etc.): _____ Unknown d) What was the address, city, and state of acquisition (if not case’s home): _____ Unknown e) What was the product expiration/best by/best before date: _____ Unknown f) What was the product lot number or code on the packaging:_____ Unknown g) Is there any remaining product? Yes No Unknown
		70. In the 10 days before becoming ill, did the patient consume any raw or unpasteurized milk products? (select all that apply): Raw milk cheese Heavy raw cream Whole raw kefir Raw butter Raw yogurt Raw kefir pet food

ICR Non-Substantive CHANGE REQUEST MEMO

		Raw milk pet food Other (specify): Unknown Refused (If yes ask sub-questions a through g, write in "Refused" if refused to answer or "NA" if question not applicable) a) What was the type (cow milk, goat milk, etc.), variety, and brand: _____ Unknown b) What was the consumption date (MM-DD-YYY): Unknown c) Where was the milk product acquired (store name, farm name, herd share, etc.): _____ Unknown d) What was the address, city, and state of acquisition (if not case's home): _____ Unknown e) What was the product expiration/best by/best before date: _____ Unknown f) What was the product lot number or code on the packaging:_____ Unknown g) Is there any remaining product? Yes No Unknown
	85. In the 10 days before becoming ill, on what days did the patient have direct or any other exposure (touch or handle pigs or touch potentially contaminated surfaces) to pigs (check all that apply)?	88. In the 10 days before becoming ill, on what days did the patient have direct or any other exposure (touch or handle pigs or touch potentially contaminated surfaces, walk through an area containing, or come within 6 feet of any pigs/hogs) to pigs (check all that apply)?
	94. Where did the direct contact with poultry occur (check all that apply)? Home	97. Where did the direct contact with poultry occur (check all that apply)? Home

ICR Non-Substantive CHANGE REQUEST MEMO

	Commercial poultry farm Agricultural fair or event Live animal market Petting zoo Veterinary care Slaughterhouse Other	Commercial poultry farm Agricultural fair or event Live animal market Petting zoo Veterinary care Slaughterhouse/Rendering facility Other
		135. In the 10 days before becoming ill, did the patient have direct contact (touch or handle) with livestock (cattle, goats, sheep, pigs, etc.)? Yes No (skip to Q.138) Unknown (skip to Q.138)
		136. Where did the direct contact with livestock occur (check all that apply)? Home Commercial farm Agricultural fair or event Live animal market Petting zoo Veterinary care Slaughterhouse/rendering facility Other
		137. What type(s) of livestock did the patient have direct contact with (check all that apply)? Cattle Sheep Goats Other
		138. In the 10 days before becoming ill, did the patient have any other exposure to (e.g., touch potentially contaminated surfaces, walk through an area containing, or come within 6 feet of) livestock? Yes No (skip to Q.141) Unknown (skip to Q.141)
		139. Where did this exposure from Q.138 to livestock occur (check all that apply)? Home Commercial farm Agricultural fair or event Live animal market Petting zoo Veterinary care Slaughterhouse/rendering facility Other
		140. What type(s) of livestock did the patient have this exposure to from Q.138 (check all

ICR Non-Substantive CHANGE REQUEST MEMO

		that apply)? Cattle Sheep Goats Other
		141. Did the patient conduct any of the following activities in the 10 days before becoming ill (check all that apply)? Work at a farm or facility where live animals are present Touch, handle, or otherwise interact with ill livestock (cattle, goats, sheep) Touch, handle, or otherwise interact with ill wild animals Drink or handle raw or unpasteurized milk Consume or handle raw or unpasteurized milk products (cheese, cream, kefir, etc.) Work in a maternity or reproductive area of a farm Handle or clean up animal stool or manure Use a pressure washer or broom in an area contaminated by animal manure or milk Operate or clean automated milking equipment Perform manual milking of animals
		142. Did the patient clean any livestock pens in the 10 days before becoming ill? Yes No Unknown
		143. Did the patient feed or water any livestock in the 10 days before becoming ill? Yes No Unknown
		144. Did the patient have direct contact with surfaces contaminated by livestock, livestock manure, livestock milk, or livestock parts (carcasses, internal organs, reproductive tissues, etc.) in the 10 days before becoming ill? Yes No Unknown
		145. What measures did the patient use to protect himself/herself when exposed to livestock (check all that apply)? None Facemask Respirators Hand gloves Eye Protection Gowns Boots Unknown Other
		146. What percentage of time did the person wear the items mentioned above while exposed to livestock (only ask about the items the exposed person mentioned in Q.

ICR Non-Substantive CHANGE REQUEST MEMO

		146)? % Facemask % Respirators % Hand gloves % Eye protection % Gowns % Boots % Other
		147. In the 10 days before becoming ill, on what days did the patient have direct or any other exposure (touch or handle or touch potentially contaminated surfaces, walk through an area containing, or come within 6 feet of) to livestock (check all that apply)? on the day of illness onset 1 day before illness onset 2 days before illness onset 3 days before illness onset 4 days before illness onset 5 days before illness onset 6 days before illness onset 7 days before illness onset 8 days before illness onset 9 days before illness onset 10 days before illness onset
		148. Did the patient report direct or any other exposure to any livestock that appeared ill in the 10 days before becoming ill? Yes, specify _____ No _____ Unknown _____
		149. Did the patient report direct or any other exposure to dead livestock in the 10 days before becoming ill? Yes, specify _____ No _____ Unknown _____
Attachment P: Novel Influenza A Virus Case Screening Form	Any wild bird/poultry contact in 10 days prior to illness onset? ☐ Yes ☐ No ☐ Unknown	Any animal exposure in 10 days prior to illness onset? ☐ Yes ☐ No ☐ Unknown
		What type(s) of animals was the patient exposed to? ☐ Horses ☐ Cows ☐ Poultry/wild birds ☐ Sheep ☐ Goats ☐ Pigs/hogs ☐ Other (1) _____ ☐ Other (2) _____ ☐ Other (3) _____ ☐ Other (4) _____
	Where did this wild bird/poultry contact occur? (select all that apply)	Where did this animal exposure occur? (select all that apply) ☐ Participated in a depopulation event

ICR Non-Substantive CHANGE REQUEST MEMO

	☐ Participated in a depopulation event ☐ Worked or lived on farm where HPAI was detected ☐ Hunted and harvested a wild bird ☐ Other, specify: _____	☐ Worked or lived on farm where HPAI was detected ☐ Hunted and harvested a wild bird ☐ Attended agricultural event/live animal market ☐ Other, specify: _____
	Any swine contact in 7 days prior to illness onset? ☐ Yes ☐ No ☐ Unknown	<i>Removed</i>
	Agricultural event/live animal market attendance in 7 days prior to illness onset? ☐ Yes ☐ No ☐ Unknown If Yes, specify name: _____	<i>Removed</i>
Attachment EE: Aggregate counts of persons exposed to highly pathogenic avian influenza (HPAI)	Total number of individuals exposed and intended to be actively monitored (associated with 2022 HPAI outbreaks)	Total number of individuals exposed and intended to be actively monitored (associated with HPAI outbreaks)
	Exposure categories: USDA/Contract Responders* State or Producer Responder* Not affiliated with Response (e.g. farm owners, workers) Other, specify: Total *an individual who participated in the confirmation, depopulation, and/or decontamination of the site.	Exposure categories: Commercial Poultry Farm Commercial Cattle Farm Backyard or Hobby Farm Other, Specify: Total
		Removed footnote defining responder Removed acronym for daily active monitoring in footnotes

Effect on Burden Estimate:

- The burden estimate will increase by 5 minutes for Attachment K due to the addition of questions for individuals reporting exposure to raw milk/milk products or to livestock. There is no change in estimated burden for the screening form or aggregate monitoring form.

Form	Approved Burden	Requested Burden
Attachment K: Human Infection with Novel Influenza A Virus Case Report Form	Respondents: (57*2) 114 Hours: 57 Costs: \$ 2,145.48	Respondents: (57*2) 114 Hours: 66.5 Costs: \$ 2,503.06
Attachment P: Novel Influenza A Virus Case Screening Form	Respondents: 57 Hours: 14.25 Costs: \$ 526.96	Respondents: 57 Hours: 14.25 Costs: \$526.96
Attachment EE: Aggregate counts of persons exposed to highly pathogenic avian influenza (HPAI)	Respondents: (52*52) 2,704 Hours: 450.67 Costs: \$ 16,963.09	Respondents: (52*52) 2,704 Hours: 450.67 Costs: 16,963.09

ICR Non-Substantive CHANGE REQUEST MEMO

Total		
	Respondents: 2,875 Hours: 521.9 Costs: \$19,644.32	Respondents: 2,875 Hours: 531.4 Costs: \$20,001.90