

## ADH Proposed Milk Bank Standards

### Summary of Public Comments and ADH Responses

1. Commenter's Name: Victoria Niklas

Commenter's Business/Agency: Prolacta Bioscience

Summary of Comment:

Classification and Labeling: That though the Health Department's proposed milk banking regulations mirror existing federal guidelines, the proposed regulations fall short specifically around safety and labeling requirements as established by FDA, in 21 CFR 100-169.

Agency's response to Comment:

ADH disagrees with commentator's legal analysis. Human Breast milk is not defined in the Code of Law in the United States and is not regulated by the FDA, including promulgation of any standards. The FDA defines both cow's milk and infant formula in Title 21: "Food and Drugs". Does not define human breast milk as food. Accordingly, 21 CFR 100-169 is inapplicable to human breast milk and specifically the subchapter for Food for Human Consumption. See 21 C.F.R. § 133.3. Also see: Mathilde Cohen, Should Human Milk Be Regulated? Vol. 9 Issue 3, UC Irvine Law Review 557 (2019).

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe.

No changes were made.

2. Commenter's Name: Victoria Niklas

Commenter's Business/Agency: Prolacta Bioscience

Summary of Comment:

Testing: ADH guidelines in their present form, do not address the risk of transmission of infectious diseases.

Agency's response to Comment:

ADH Guidelines are based upon Standards adopted by the Human Milk Banking Association of North America (HMBANA). HMBANA has been referred to as the "gold standard in the profession." See: Mathilde Cohen, Should Human Milk Be Regulated? Vol. 9 Issue 3, UC Irvine Law Review 557 (2019). However, ADH's initial draft did not "wholesale" incorporate those Standards. Based on consideration of stakeholder concerns, ADH will further and thoroughly explore the Public Health issues raised with

the potential for changes to the current draft completed prior to the quarterly Board of Health meeting in April 2020.

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe.

Changes are currently under consideration.

3. Commenter's Name: Victoria Niklas

Commenter's Business/Agency: Prolacta Bioscience

Summary of Comment:

Traceability: Prolacta encourages the Department to consider an absolute traceability requirement for all donor milk and donor-milk derived products.

Agency's response to Comment:

ADH Guidelines are based upon Standards adopted by the Human Milk Banking Association of North America (HMBANA). HMBANA has been referred to as the "gold standard in the profession." See: Mathilde Cohen, Should Human Milk Be Regulated? Vol. 9 Issue 3, UC Irvine Law Review 557 (2019). However, ADH's initial draft did not "wholesale" incorporate those Standards. Based on consideration of stakeholder concerns, ADH will further and thoroughly explore the Public Health issues raised with the potential for changes to the current draft completed prior to the quarterly Board of Health meeting in April of 2020.

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe.

Changes are currently under consideration.