Quantitative risk assessment for shigatoxin producing *E. coli* in bulk milk sold directly from producer to consumer.

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Definitions

- **Hazard:** **A hazard is an agent having an adverse effect on the public health of the human population and may pose a short term, chronic, or fatal risk to a person**

Definitions

- **Risk:** **A function of the PROBABILITY of an adverse health effect and the SERVERITY of and adverse health effect.**

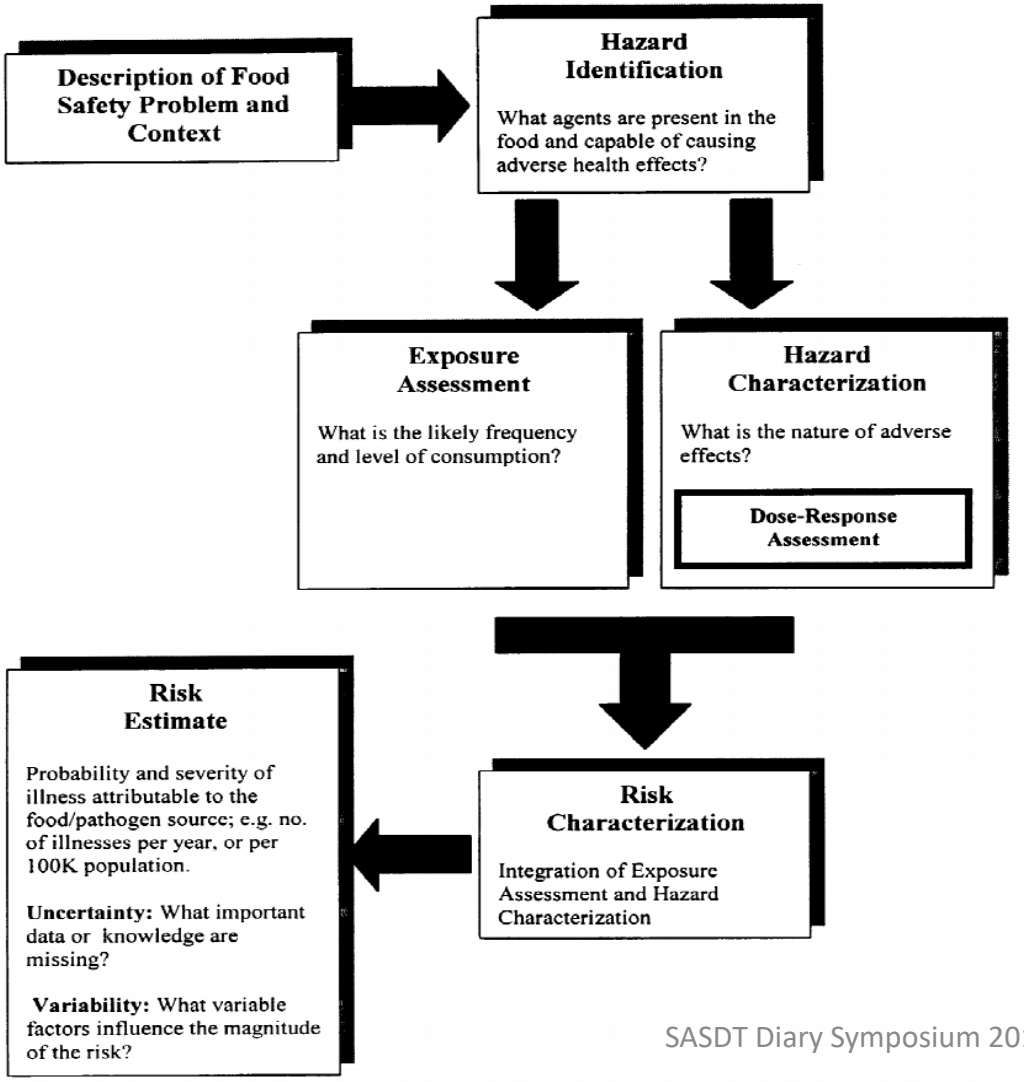
RISK = PROBABILITY X IMPACT OF THE DAMAGE

Definitions

- **Risk analysis:** **The process of 3 distinct but closely linked components**

Definitions

- **Risk assessment:** **The measurement of risk and identification factor that influences it. Is an independent scientific process consisting of the following:**



- **Over the years, shiga toxin producing *Escherichia. coli* (STEC) have globally evolved from clinical novelty to primary food safety and public health concern** (Khan et al., 2002).
- ***Long-term sequelae of STEC infections range from mild diarrhoea and intestinal discomfort to serious complications such as haemolytic-uremic syndrome (HUS) and thrombotic thrombocytopenic purpura (TTP).***
- **STEC O157 has been implicated in many food borne disease outbreaks. However, emerging non-O157 serotypes are becoming important in public health** (Khan et al., 2002; Delignette-Muller et al., 2008).
- **Documented milkborne disease outbreaks have been linked to consumption of both raw and pasteurised bulk milk contaminated with STEC** (CDC, 2007).
- **Epidemiological statistics on STEC in food in Africa are imprecise and the studies are few.**
  - In SA, there are no official data existing on the prevalence of STEC linked to contaminated food. However, studies have indicated prevalence of STEC isolated from humans and livestock faeces, water and food: ranging from 10 – 50 % (Aijuka et al., 2014; Iweriebor et al., 2015; Ndlovu et al., 2015; Ntuli et al., 2017).

- **A survey on producer-distributor bulk milk (PDBM) in SA revealed high levels of *E. coli*** (Ntuli et al., 2016; 2017).
- **PDBM constitutes approx. 2% of milk produced and sold in SA.**
  - We reported a diversity of STEC seropathotypes, (with different shigatoxin virulence factors, multi drug resistant and extended-spectrum β-lactamases (ESBLs) producing capacity in the PDBM (Ntuli et al., 2016; 2017).

- **Owing to the lack of epidemiological data, the burden of pathogenic *E. coli* linked to consumption of PDBM in SA has not been assessed.**

- **To gain an insight on the accurate estimates of the actual risk posed by consumption of PDBM contaminated by pathogenic *E. coli*, A QUANTITATIVE MICROBIAL RISK ASSESSMENT MODELING is one of the practice to evaluate food health risks and control.**

Research Objective

- **This study was envisaged to estimate HUS risk associated with consumption of STEC contaminated PDBM and estimate the resulting burden of illness that may be associated with consumption of PDBM in SA.**

HAZARD IDENTIFICATION

J. Dairy Sci. 99:9534–9549
http://dx.doi.org/10.3168/jds.2016-11403

Characterization of *Escherichia coli* an in producer-distributor bulk milk

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International Dairy Journal 66 (2017) 126–134

Contents lists available at ScienceDirect

International Dairy Journal

journal homepage: www.elsevier.com/locate/idairyj

Extended-spectrum β-lactamase, shigatoxin and haemolysis c of O157 and non-O157 *E. coli* serotypes from producer-distribut milk

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- **We reported STEC O157 and emerging non-O157 STEC O2, O9, O20, O43, O64, O68, O83, O112, O155 in PDBM in SA.**
- **Lately, several milkborne disease outbreaks have been incriminated to consumption of raw milk contaminated with STEC in the EU and US, especially raw milk sold directly from producer to the public.**

EXPOSURE ASSESSMENT

- **Modular Process Risk Model (MPRM) frame work was used for exposure assessment** (Nauta, 2002).

Stage 1

- **Field survey:**

A survey was conducted in urban and peri-urban parts of Pretoria in SA (one of the PDBM sampling areas) with the aim of getting an insight on the typical flow of PDBM from outlets to consumer and PDBM consumption patterns.

A questionnaire was developed to capture the following information:

(i) Average volumes of PDBM produced or received at outlets per-day,

(ii) PDBM handling practices and storage conditions at outlets,

(iii) Average volumes of PDBM sold per-day,

(iv) PDBM handling practices during transportation to home,

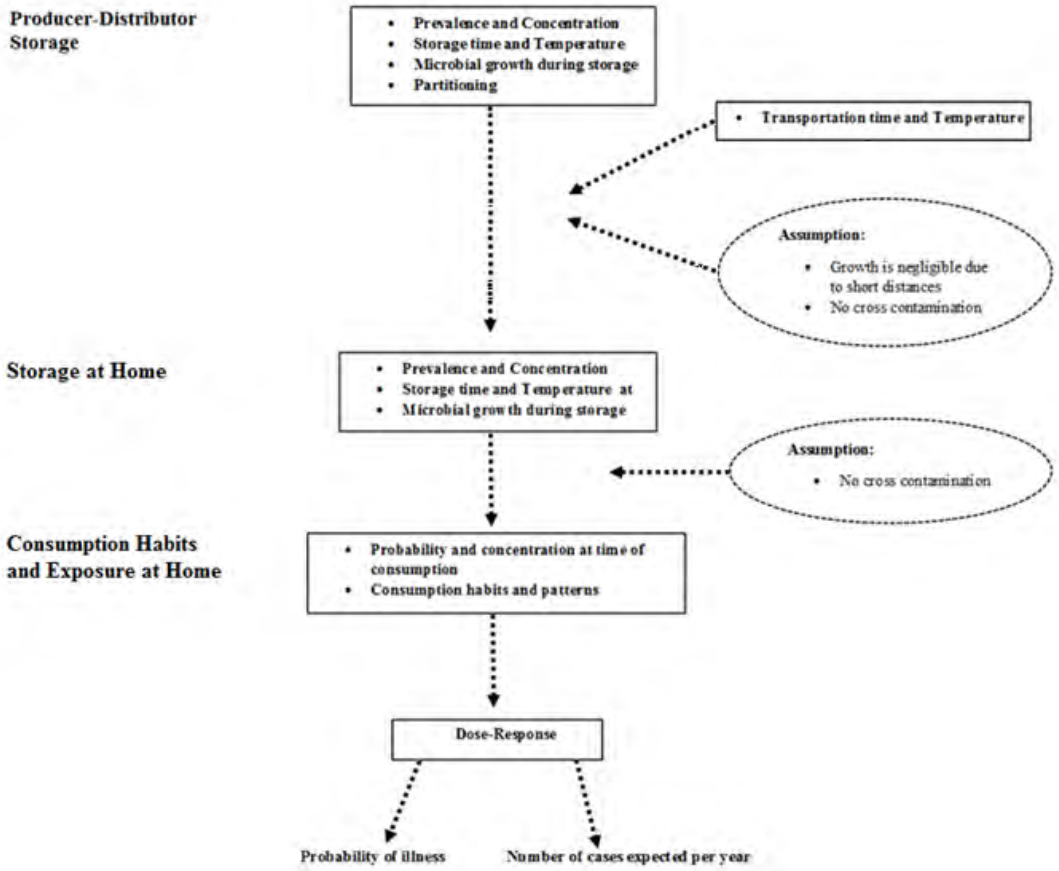
(v) Consumer handling practices and storage conditions, and also consumption patterns.

A total of 15 PDBM outlets and 80 consumers were interviewed and the information was used as input for the models.

EXPOSURE ASSESSMENT AND DOSE-RESPONSE

Stage 2

Schematic overview of the quantitative risk assessment model for shigatoxin producing *E. coli* in producer-distributor bulk milk.



Research Approach

RISK CHARACTERISATION

Stage 3

- **Probability of HUS per-serving was computed by combining the dose estimate and contamination prevalence.**

- **Number of cases per year was calculated by multiplying the probability of HUS per-serving and the number of serving per year for each target age group.**

Research Approach

SIMULATION AND ANALYSIS

- **Monte Carlo simulations were carried out the risk analysis software @Risk 7.5 (Palisade Corporation, Ithaca, USA).**
- **Sensitivity analysis**
- **Milk handling scenario analysis**

Estimation of shigatoxin producing *E. coli* concentration per-serving in raw and pasteurised producer-distributor bulk milk.

Parameter / percentile	Estimated level of STEC (cfu/per-serving)	
	Raw PDBM	Pasteurised PDBM
Minimum	4.06×10^{-4}	2.95×10^{-4}
Mean	4.06×10^{2}	3.66×10^{2}
Maximum	6.09×10^{3}	6.42×10^{3}
5th	5.84×10^{-3}	5.12×10^{-3}
50th	0.42	0.37
95th	1.88×10^{3}	1.69×10^{3}

- 67% of consumers boiled milk before consumption.
- The quantity of STEC that a consumer was exposed to in a single serving of milk was a function of the initial concentration of STEC in PDBM at PD outlets, and the subsequent effects of handling and storage along the milk chain.

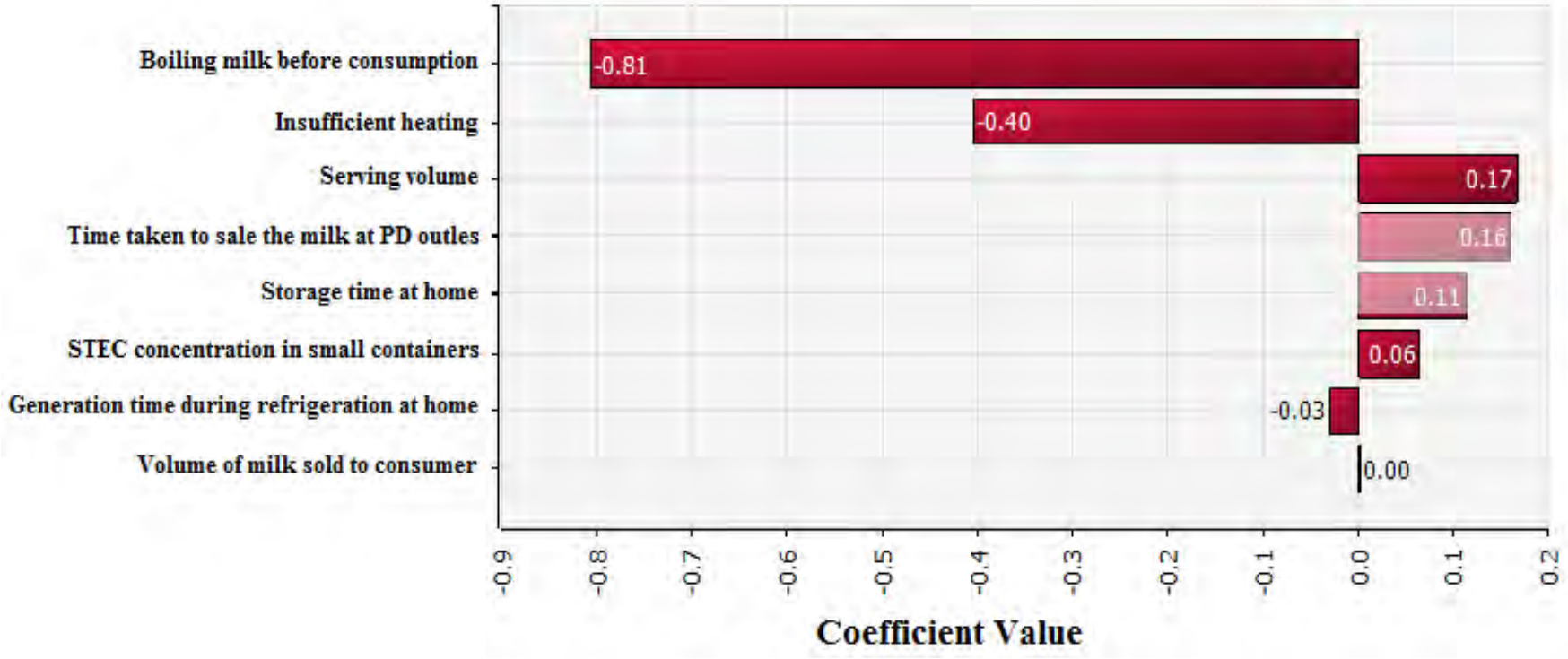
Probability of illness per serving and number of haemolytic-uremic syndrome cases per-year with consumption of raw and pasteurised producer-distributor bulk milk.

Milk category	Population	Probability of illness per-serving Median (5^{th}, 95^{th}) percentiles	Number of cases per-year Median (5^{th}, 95^{th}) percentiles
Raw PDBM	Under 5 years	5.4×10^{-4} (7.5×10^{-6}, 0.91)	52 (0.68, 1.3×10^{5})
	Above 5 year	1.0×10^{-4} (1.4×10^{-6}, 0.37)	3.2 (0.04, 1.5×10^{4})
Pasteurised PDBM	Under 5 years	4.8×10^{-4} (6.7×10^{-6}, 0.82)	47 (0.60, 1.2×10^{5})
	Above 5 year	9.0×10^{-5} (1.3×10^{-6}, 0.33)	2.9 (0.03, 1.3×10^{4})

*Values are the median, 5^{th} and 95^{th} percentile obtained after 100 000 iteration, using @ risk 7.5 in both raw and pasteurised PDBM
*The values for number of cases were calculated for every 100 000 portions of PDBM consumed

- The model predicted higher risk of HUS cases in consumers of raw than pasteurised PDBM.
- In simulations where all consumers boil milk before consumption, no risk was calculated for both raw and pasteurised PDBM.
- Considered consumers who insufficiently heat the milk before consumption, the highest median probability of illness per-serving was noted in children under 5 years. Furthermore, the highest number of HUS cases were observed in children under five years of age.

Sensitivity analysis between estimated probability of illness after one serving of producer-distributor bulk milk and important predictive factors along the value chain.



- In the current study, the risk of infection and the subsequent development of HUS was most influenced by serving volumes followed by time taken to sell the milk at PD outlets.

Possible handling scenarios and their associated effects in reducing exposure per-serving to shigatoxin producing *E. coli* to consumers who do not boil producer-distributor bulk milk.

Handling procedures	Reduction in concentration of STEC per-serving (%)	
	Raw PDBM	Pasteurised PDBM
[a]Storage and handling at 4°C:		
PD outlets	23.1	19.6
Transportation home	8.0	9.7
Home refrigeration	13.3	11.9
[b]Time taken to sell the milk:		
5 hr	54.2	56.0
6 hr	51.8	54.3
7 hr	44.0	45.1
[c]Time taken to consume all the milk at home:		
½ a day	55.8	57.1
1 day	43.5	46.4
2days	34.9	37.2
a (4°C)+b (5hr)+c (½ a day)	83.2	88.5

- Reducing time taken to consume all the milk after arriving to half a day, was the most effective single handling practice.
- A combination of PDBM handling practices (storage at 4°C throughout the whole chain, time taken to sell the milk (5 hr) and time taken to consume the milk (half a day)) along the product value chain had more impact in reducing the risk of infection and probability of illness.

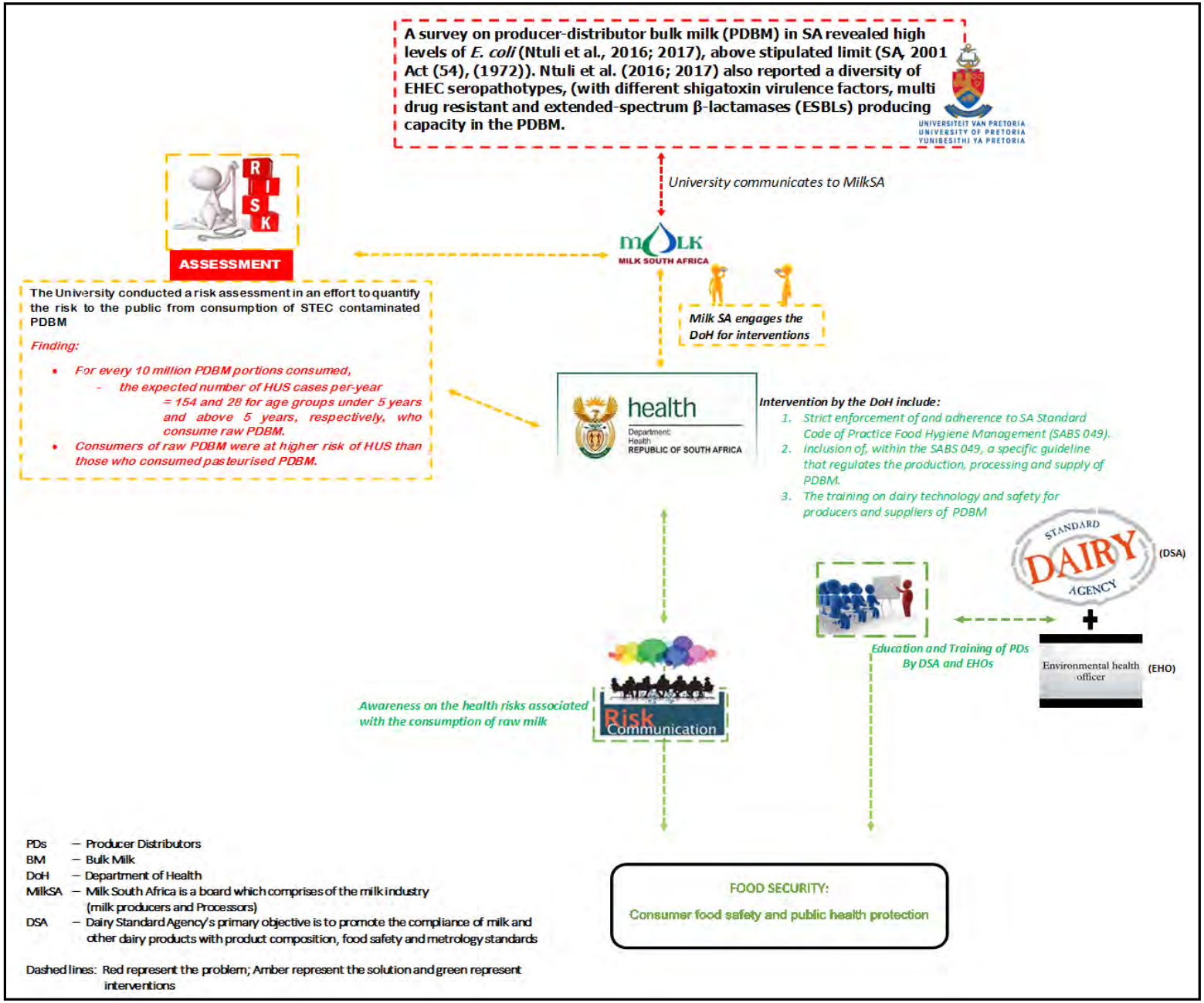
Conclusions

- **A higher risk of HUS cases per-year was estimated in raw than pasteurised PDBM.**
- **We also observed a higher risk of STEC infections in age below 5 years in comparison to age group above 5 years.**
- **The model estimates show that the public health significance of HUS cases due to milk handling along the food chain and is explicitly influenced by consumer behavior.**
- **Time taken to sell the milk at PD outlets and PDBM storage time at home had the greatest effect on the probability of HUS and the annual number of cases.**

Conclusions

- **This study recommends strict enforcement of and adherence to SA Standard Code of Practice Food Hygiene Management (SABS 049), which regulates food hygiene in the dairy industry, especially for PDs.**
- **We also recommend the inclusion of, within the SABS 049, a specific guideline that regulates the production, processing and supply of PDBM.**
- **Furthermore, the training on dairy technology and safety for producers and suppliers of PDBM by the Department of Health, in collaboration with environmental health officers (in the different municipalities across SA) and non-governmental organisations, such as the Dairy Standard Agency needs to be strengthened to improve public health and safety.**
- **The raising of awareness on the health risks associated with the consumption of raw milk for, particularly, consumers of raw PDBM, also needs to be scaled-up for them to make informed decisions when buying milk.**
- **The awareness will indirectly encourage consumers to buy certified raw milk.**

A collaborative effort of academia, industry, non-Governmental Organisation and the Government to improve public health and safety associated with Shigatoxin producing *E. coli* in Producer -Distributor Bulk Milk.



Acknowledgements

- **Milk SA**
- **SASDT**
- **NRF**


Thank you