Malaysian Applied Biology (2023) 52(1): 109-121
https://doi.org/10.55230/mabjournal.v52i1.2528

Research

Identification of Sensitive Raw Materials at A Milk Preparation Room of A Neonatal Intensive Care Unit in the Canselor Tuanku Muhriz Hospital

Mahirah Mohamad[1], Shareena Ishak[2,*] and Norrakiah Abdullah Sani[1,*]

1. Department of Food Sciences, Faculty of Science and Technology, Universiti Kebangsaan Malaysia, 43600 UKM Bangi Selangor, Malaysia
2. Department of Paediatric, Canselor Tuanku Muhriz Hospital, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras, Kuala Lumpur, Malaysia
*Corresponding authors: shareena@ppukm.ukm.edu.my ; norrasani@yahoo.co.uk

ABSTRACT

The implementation of a Hazard Analysis and Critical Control Point (HACCP) system in infant milk preparation can prevent and reduce the risk of bacterial contamination in infant feedings. Therefore, it is very important to determine the sensitive raw materials (SRM) in a milk room of a neonatal intensive care unit (NICU) to prevent contamination that can affect the safety of milk feeding. This study was conducted to identify the SRM at the milk preparation room of a NICU in the Canselor Tuanku Muhriz Hospital, Cheras, Kuala Lumpur, Malaysia. SRM were identified via HACCP system decision tree by the Malaysian Standard (MS1480:2007). The results showed that donor expressed breast milk (DEBM), expressed breast milk at home (EBMH), freshly expressed breast milk (FEBM) and powdered infant formula (PIF) were identified as SRM. Expressed breast milk (DEBM, EBMH, FEBM) were known as non-sterile milk which were able to transmit pathogenic microorganisms such as *Klebsiella pneumoniae* and *Pseudomonas aeruginosa* derived from the mother or donor. PIF is also not sterile that are associated with *Cronobacter sakazakii* and *Salmonella* infections causing serious illnesses among premature and infants. Ready to feed milk (RTF) is classified as non-sensitive material as it is sterile, free from bacterial contamination and safe for high-risk infant's feeding compare to PIF. Preventive measures were applied to control the significant hazards in all identified SRM to ensure the final product (milk) is safe for consumption.

Key words: HACCP, milk room, neonatal intensive care unit (NICU), sensitive raw materials

Article History
Accepted: 1 April 2023
First version online: 3 April 2023

Cite This Article:
Mohamad, M., Ishak, S. & Abdullah Sani, N. 2023. Identification of sensitive raw materials at a milk preparation room of a neonatal intensive care unit in the Canselor Tuanku Muhriz Hospital. Malaysian Applied Biology, 52(1): 109-121. https://doi.org/10.55230/mabjournal.v52i1.2528

INTRODUCTION

Hazard Analysis and Critical Control Points (HACCP) is an internationally recognised system widely used in the food industry. HACCP aims to identify, prevent, eliminate or reduce any biological, physical or chemical hazards that would be likely to occur in food operations to an acceptable level (CAC, 1997). The Ministry of Health Malaysia (MOH) has introduced the HACCP system to be implemented in hospitals' kitchens of all government hospitals in Malaysia because of high concern about the level of food safety served to the high-risk group (patients) in hospitals (MOH, 2010).

Most admitted patients received meals that has been prepared by hospitals' kitchens except for patients warded in the special ward such as the neonatal intensive care unit (NICU). Neonates and infants in the NICU only receive nutrition (milk) that has been prepared commonly at the NICU. The safety of milk feedingthe in NICU is very important because infants have a low immune system and easily expose to the risk of infection as they are premature and sick newborns. Expressed breast milk is known as not sterile milk and can transmit pathogenic bacteria either from the mother or the NICU environment (Law *et al.,* 1989; Jones, 2001). Many cases were reported of bacterial contamination of breast milk in NICU (Boo *et al.,* 2001; Karimi *et al.,* 2013; Gad *et al.,* 2021). A case of bacteremia among premature infants caused by contaminated expressed breast milk was reported in 1999 in this NICU (Boo *et al.,* 2000) and also meningitis cases were also reported in the NICU of Pennsylvania in 2016 due to contaminated breast milk with *Cronobacter sakazakii* (Bowen, Wiesenfeld & Kloesz, 2017). Bacterial contamination of milk feeding also occurred in this NICU with *Acinetobacter*, *Bacillus* spp., *Citrobacter freundii* and

Klebsiella found in expressed breast milk (Mahirah, 2022).

The milk feeding in the NICU is mainly prepared in a separate room (centralised milk room) instead of at the bedside. It is found that a centralised milk room can reduce the risk of microbial milk contamination incidence than the bedside (Steel *et al.,* 2008). The milk room is a specific room in the NICU which is allocated for infant milk storage and preparation (ADA, 2011). The HACCP system has been suggested to be implemented in infant milk feeding preparation room to minimize and prevent the risk of potential bacteria that can contaminate the milk feedings (Best, 2008; Bankhead *et al.,* 2009; Almeida *et al.,* 2009). This concludes the importance of implementing the HACCP system in NICU.

HACCP system implementation also has been recommended in human milk bank operation for the safety and quality assurance of donor milk (NICE, 2010; HMBASA, 2011; HMBANA, 2020) Several studies reported that HACCP system has been implemented for on-site hospital preparation of infant formula in Brazil (Almeida *et al.,*1999) and for expressed breast milk in NICU of Belgium hospital (Cossey *et al.,* 2011). A study by Cossey *et al.,* (2011) suggested the implementation of a (HACCP) system can improve the safety of EBM in the NICU. However, Malaysia hospital has not yet implemented HACCP system in the milk room of NICU. The hospital in this study practice safe milk preparation and handling based on Standard Operating Procedure (SOP). Thus, the HACCP system should also be implemented in the milk room of NICU in Malaysia to ensure the milk fed to the high-risk infants is safe for feeding. HACCP system consists of seven principles which are: Principle 1 - conduct a hazard analysis, Principle 2 - determine the critical control point (CCP), Principle 3 - establish critical limit (CL), Principle 4 - establish a monitoring system to control the critical control point, Principle 5 - establish the corrective action to be taken when the critical control point is out of control, Principle 6 - establish verification procedures to ensure that the HACCP system is effective, and Principle 7 - establish record keeping and documentation procedures (CAC, 1997). These seven principles aim to prevent hazards and address food safety throughout the preparation process instead of inspecting the final product. This systematic approach is important to assess risks in NICU setting and results to produce high-quality and safety of milk feeding to infants.

Hazard analysis (Principle 1 of HACCP) consists of hazard analysis of raw materials and processes. Hazard analysis aims to determine the potential hazards that are reasonably likely to occur and to identify the significant hazard that occur in an operation. Potential hazard consists of biological, chemical or physical contaminants in food that can risk the consumer and cause adverse health effect (FAO, 1998). Meanwhile, significant hazard analysis is based on severity and the likelihood of occurring. Severity is the consequence of hazards which categorised as high-severlife-threatening, moderate-severity hazards (severe or chronic) and low-severity hazards (moderate or mild). The likelihood of a hazard is the probability that the hazard will contaminate human milk (PATH, 2019). It can be categorised as high, moderate or low. Significant hazards are identified with severity/likelihood (high/high, high/moderate, or moderate/high risk) (FAO, 1998). Principle 2 in HACCP is a CCP determination at the process or step to eliminate, prevent and reduce food safety hazards to an acceptable level (FAO, 1997). At these CCPs, failure to follow the standard operating procedures could result in unsafe milk and harm to infants (PATH, 2019). Sensitive raw material (SRM) is also identified at this stage by using decision tree for raw material or packaging. SRM can be a material forming part of a product (additives, primary produce, packaging) and similar materials that could result in an unacceptable food safety risk to consumers and need to be controlled (MS 1480:2007). Therefore, SRM identification is very important to ensure the final product is safe and HACCP plan is applied correctly (effective).

The purpose of this study was to identify the SRM in a milk room by referring to MS 1480:2007 decision tree for materials. Codex guidelines only provides the decision tree for the process step whereas MS 1480:2007 provides both decision tree for sensitive materials and processes. According to MS 1480:2007, the sensitivity of raw materials must be identified as SRM or non-SRM and not as a critical control point (CCP) or control point (CP) which has been practiced by many industries (Mohd Bakri *et al.,* 2017). Determination of SRM in the milk room is very important to decide which raw material is sensitive and needs to be controlled. Any hazards that are not properly controlled can cause serious effects on infant's health. Lataf *et al.* (2020) stated that SRM identification can prevent product spoilage that could influence food safety. Identification of the SRM in this study can prevent bacterial spoilage of milk feeding and increase the level of milk safety in the NICU. There are no reported studies on identification of SRM in milk preparation room of NICU hospital. Many previous studies discussed the importance of proper handling and preparation of milk in NICU (Steel & Short, 2008; Turck, 2012) and did not specifically discuss on SRM in NICU milk rooms. Therefore, this study was conducted to identify the SRM in the milk preparation room of NICU.

MATERIALS AND METHODS

This study was conducted with ethics approval (UKM 1.5.3.5/244/FST-2015-013) and the milk room NICU can be accessed to monitor the milk preparation and handling and interviewed the nurses and milk handlers. The milk preparation room is situated in the NICU of the Canselor Tuanku Muhriz Hospital (HCTM). The activities in this room were observed with the head of nurses and milk handlers to get the information regarding milk preparation starting from receiving of raw materials, storing, pasteurising, warming and feeding. All raw materials information was collected for hazard analysis. The preparation of milk feedings in the milk room is handled by a milk handler. Milk handler is fully responsible in the milk room to store and prepare milk before the nurses collect milk during feeding time.

Hazard analysis and determination of SRM were based on the international report, standard requirement, scientific data of journal articles and guidelines. A hazard analysis worksheet for raw material/ packaging material (MS 1480:2007) was used to conduct a hazard analysis of raw material (Table 1). The first column in this worksheet was used to list all raw materials in the milk preparation room of the NICU and then identified all the potential hazards (biological, chemical or physical) that were reasonably present in the raw materials in the second column. The rationality for the inclusion or exclusion of potential hazards as hazards were presented in column 3. The information provided for the rationale of hazard inclusion or exclusion was

adopted from a previous study (Bakri *et al.,* 2015). The significant hazards were determined by evaluating the severity and likelihood of occurrence (risk analysis) and presented in the column. The preventative measure (column 5) is a control measure that was applied to control the hazard. The significant hazards in raw materials were then determined as SRM or non-SRM the via decision tree (MS 1480:2007) in column 6.

The determination of SRM in this study was referred to in the decision tree for raw materials (MS1480:2007) (Figure 1). This decision tree for raw materials consists of three questions; Question 1 aims to identify the significant hazards in all raw materials and prevent missing potential hazards in hazard analysis. All raw materials involved in the preparation of milk feeding must be identified. Question 2 describes the process that needs to be done to eliminate hazards such as heat treatment, chilling or radiation (Wallace *et al.,* 2011). Question 3 explains about cross-contamination risk to raw material during storage, processing and handling. The SRM was then identified as SRM, not as CCP (critical control point).

RESULTS AND DISCUSSION

During the observation at the milk preparation room, it was found that donor expressed breast milk (DEBM), freshly expressed breast milk (expressed at NICU, FEBM), expressed breast milk at home (EBMH), powdered infant formula (PIF), ready to feed milk (RTF), supplements (human milk fortifier, protein powder, Carborie and medium-chain triglyceride (MCT) oil and water were identified as raw materials in this NICU. DEBM and FEBM will undergo pasteurisation and turn into pasteurised expressed breast milk (PEBM) as the final product. Packaging materials such as milk bottles and pacifiers were also included as raw materials (packaging) and were not determined as sensitive materials, as there were no biological hazards found in cleaned bottles and pacifiers in this NICU. However, control measures should be taken into consideration. Bottles and pacifiers were cleaned and sanitised according to the sanitation standard operating procedure (SOP) to prevent the presence and occurrence of possible biological hazards.

Some milk feedings were added with supplements such as human milk fortifier, protein powder, Carborie and MCT oil. The types of milk feedings given to the infants were according to the prescriptions from the neonatologists/ paediatricians. Based on the hazard analysis of seven raw materials in the milk room of this NICU (Table 1), there were four raw materials identified as SRM, which were DEBM, FEBM, EBMH and PIF. These four raw materials were considered as SRM because of the serious illnesses related to the pathogens in raw materials that could affect the infants in the NICU.

Sensitive raw materials

Donor expressed breast milk

Donor expressed breast milk (DEBM) is the best alternative mother's breast milk for sick infants and premature infants because some of the preterm mothers were unable to provide a sufficient volume of breast milk for their own infants during hospitalisation. However, the potential risk may exist when the milk can be contaminated with hazards such as viruses and pathogenic bacteria. Potential biological hazards e.g. Human Immunodeficiency Virus (HIV), Human T-cell Lymphotropic Virus (HTLV) type I or II, Hepatitis B or C, Syphilis, *Pseudomonas aeruginosa, Klebsiella* spp. and *Staphylococcus aureus* (Baumer, 2004; NICE, 2010; PATH, 2016) and chemical hazards such as nicotine, drug and alcohol can be transmitted to the infants through breast milk from the donor (Liston, 1998; Hartmann *et al.,* 2007; NICE, 2010 Donor screening is important to prevent potential hazards to infants caused by inadequate donor screening or the donor is a smoker, under nicotine replacement therapy (NRT) or taking alcohol and drugs (PATH, 2019). Nicotine and illegal drugs such as heroine, marijuana and cocaine in human milk can cause potential harm to infants. As a result, DEBM was identified as SRM. Potential donors with positive HIV, HTLV or II, Hepatitis B or C, Syphilis or a smoker and under NRT or taking alcohol and drugs are ineligible to donate milk.

The risk of potential hazards from pathogenic bacteria and viruses in the donor milk can be reduced through pasteurisation. DEBM in this NICU was pasteurised at 62.5 °C for 30 minutes to determine as PEBM during final feeding. After pasteurisation, the donor PEBM were stored in a chiller (0-5 °C) before feeding time. Although the DEBM in this NICU was pasteurised, the pathogenic bacteria may exist due to several factors such as improper storage (storage temperature fluctuation), inadequate pasteurisation resulting from pasteuriser malfunctioning and contamination of milk pasteuriser (Roberts & Severn, 1978; Gras-Le Guen *et al.,* 2003). Therefore, this DEBM was identified as SRM and needs to be controlled. Assessment test and serological test for potential donor are needed as a preventive measure. It is needed to prevent the significant hazard from the donor to be transmitted to the infants via contaminated milk. Storage temperature and pasteuriser (condition and cleanliness) also should be monitored frequently to prevent bacterial contamination during milk preparation. Previous study found that storing breast milk at temperatures above 4°C increased the risk of bacterial contamination and infection in hospitalized infants (Lucas *et al.,* 1992) and *P. aeruginosa* contamination risk may occur due to contaminated pasteurizer (Brown *et al.,* 2000; Gras -Le Guen *et al.,* 2003).

Freshly expressed breast milk (expressed at NICU)

Freshly expressed breast milk (FEBM) is breast milk that was expressed by the infant's own mother at the NICU and been fed to the infants without heat treatment such as pasteurisation. The mothers were unable to directly breastfeed because some sick infants or newborns have difficulties sucking and they receive milk via feeding tubes. Mother will express milk with an electric pump at a designated area for pumping in the NICU. The FEBM can be kept refrigerated at 0-5 °C for up to 48 hours.

FEBM is rarely sterile and normally contains bacteria originating from the maternal skin, mother's nipple and also may contain potential pathogens (Ogundele, 2000). Based on a research review by Jeurink *et al.* (2013), FEBM contains varieties of microorganisms including viruses, pathogenic and non-pathogenic bacteria, mycobacteria and fungi. FEBM contamination may occur by several factors such as unhygienic expressing and contaminated equipment (breast pump). Furthermore, Gransden *et al.* (1986) indicated that the breast

pump was an important source of bacterial contamination of breast milk. The study conducted by Boo *et al.* (2001) confirmed that manual expression (using hands) had lower risk of contamination than expressed breast milk using a breast pump. *Enterobacteriaceae* spp. such as *Klebsiella* spp. and *Staphylococcus coagulase, Escherichia coli* and *Streptococcus faecalis* are reported in mothers' breast milk via mechanical expression (Mense *et al.,* 2013). *Klebsiella* spp. has been found in human milk at NICU and caused bacteraemia among premature infants (Donowitz *et al.,* 1981).

Bacterial contamination from the breast pump, mother skin (nipple) and incorrect storage temperature are the factors that justify the inclusion of FEBM as a hazard. FEBM may become contaminated by microorganisms either through expression with a contaminated breast pump (Gransden *et al.,* 1986; Boo *et al.,* 2001, Mense *et al.,* 2013) or through contact with the mother's skin (nipple) and incorrect storage temperature (Ogundele, 2000). These factors justify the inclusion of FEBM as a hazard. Therefore, nurses should monitor the expression technique of mothers at the NICU to prevent milk contamination (preventive measure). Nurses should advise and teach mothers how to express milk aseptically, especially for new mothers. FEBM was identified as an SRM because the significant hazards presence in the FEBM needs to be controlled as it does not undergo a pasteurisation process to kill the hazards out of the milk. FEBM should be stored refrigerated athe t correct temperature (0-5 °C) to prevent bacterial growth in milk.

Expressed breast milk at home

EBMH is the expressed breast milk that has been expressed at home. The infant's mother will bring the EBMH to the NICU and it will be kept frozen at -18 °C to -25 °C. Rozolen *et al.* (2006) report that the EBMH may not be suitable for feeding infants admitted in Brazil's NICUs, unless it is pasteurised. The EBMH in this NICU was pasteurised at 62.5 °C for 30 minutes, similar to the DEBM.

Klebsiella spp., β-hemolytic *Streptococci, S. aureus* including MRSA, *Proteus* spp. and *Pseudomonas* spp. are commonly found in EBM and may infect infants (Novak *et al.,* 2000; Perez *et al.,* 2007; Nakamura *et al.,* 2016). *P. aeruginosa* in breast milk has been linked to nosocomial infection in NICU (Mammina *et al.,* 2008). Based on the study by Karimi *et al.* (2013), about 94.7% of contaminated breast milk is milk expressed at home. EBM collected at home by breast pump had high rates of contamination with staphylococci and Gram-negative bacteria (Boo *et al.,* 2001). Meanwhile, Davidson *et al.* (1979) also found that milk expressed at home had a higher infection than that expressed at the hospital. The contaminated equipment used for expressing breast milk at home or during transportation may result in a higher level of bacterial contamination in the milk compared to the contamination level found in milk expressed at the hospital. The microbial contamination of EBMH can occur due to unhygienic expressing techniques, improper storage temperature, and during transportation (Gad *et al.,* 2021). Additionally, contaminated breast pumps or equipment have been identified as another potential source of contamination (Boo *et al.,* 2001; Haiden *et al.,* 2016). These factors justify the inclusion of EBMH as a hazard.

The chemical hazard of paraffin in EBMH is excluded as it seldom occurs. Mothers are advised to avoid using hand lotion containing paraffin during expressing milk. Pasteurisation is necessary to breast milk at home to destroy any harmful bacteria or viruses that may be present in the milk. However, microbial contamination can happen if EBM is not well pasteurized or the pasteurised milk is stored improperly. EBMH was identified as SRM because serious illness related to potential pathogens could happen to the infants caused by inadequate pasteurisation and incorrect storage temperature. It is very important to have a well-functioned pasteuriser and a validated pasteuriser process to prevent milk spoilage. The temperature of milk storage also must be monitored regularly to control bacterial growth.

Powdered infant formula

Powdered infant formula (PIF) is made from cow milk or soy milk, water, carbohydrate and additional nutrients to provide the same nutrients like human milk (Stevens *et al.,* 2009). It is also considered as milk substitute for human milk. PIF is also known as non-sterile milk and may be intrinsically contaminated with pathogens that can cause serious illness in infants (Angulo *et al.,* 2008).

PIF may be associated with *Cronobacter sakazakii* and *Salmonella* spp. infection among infants (CAC, 2008). Many cases had been reported related to *Cronobacter* infections from contaminated PIF (Bowen & Braden, 2006). Contamination of PIF can occur at manufacturing facilities, during PIF reconstitution with contaminated water, or during inappropriate storage of reconstituted milk (Kalyantanda *et al.,* 2015). *Cronobacter sakazakii* also has been found in PIF with 12.5% prevalence in 72 PIF samples in Malaysia (Norrakiah *et al.,* 2014). *C. sakazakii* has been linked to life-threatening infections in infants such as sepsis, necrotizing enterocolitis (NEC), and meningitis (FAO/WHO, 2008; Chenu & Cox, 2009; Hunter & Bean, 2013; Holy & Forsythe, 2014). Contamination of *C. sakazakii* may occur in NICU during reconstituted PIF with contaminated water, during feeding (using contaminated bottles and feeding tubes) and at improper temperature for storage (Hunter & Bean, 2013).

World Health Organization (WHO) have recommended the safe preparation, handling, and storage of PIF guidelines to minimize the risk of infection (FAO/WHO, 2007). This guideline proposed that the temperature of hot water should be more than 70 °C during reconstitution of PIF to eliminate the risk of *C. sakazakii* infection. Meanwhile, *Salmonella* spp. has also been associated with Salmonellosis among infants that are caused by contaminated PIF (Rowe *et al.,* 1987; CDC, 1993; Usera *et al.,* 1996; Threlfall *et al.,* 1998; Park *et al.,* 2004). Contamination of *Salmonella* spp. in PIF possibly occurs during preparation at the hospital with poor hygiene practices and incorrect storage conditions of reconstituted milk (FAO/WHO, 2006). PIF contaminated with *Salmonella* was found in an opened package of formula which highlighted the potential for contamination by the consumer (Park *et al.,* 2004).

The temperature of reconstituted PIF should not be more than 5 °C to prevent the growth of *Salmonella* spp. during refrigeration. A study by Azevedo *et al.* (2005) reported that refrigeration storage above 10 °C is

an ambient temperature for *Salmonella* growth in reconstituted PIF. Similar to *C. sakazakii,* reconstituting PIF at a temperature of more than 70 °C would prevent *Salmonella* infection from PIF (FAO/WHO, 2006). PIF is identified as SRM because it is not a sterile product, contains significant hazards and exposes to a high contamination risk during milk preparation. *Cronobacter sakazakii* and *Salmonella* spp. infection could be life threatening to infants can be caused by contaminated PIF. Human milk including donor human milk, fortifiers and infant formula are SRM that may be present in milk room of NICU, thus extra attention on hygiene, safety, and quality control are needed for the safety of infants (American Academy of Paediatrics, 2012).

Non-sensitive raw materials

Ready to feed milk

Ready to feed milk (RTF) is a commercial sterile milk for neonates as an alternative to mother's and donor's breast milk. RTF is safer than PIF and suitable for high-risk infants such as infant with low birthweight, vulnerable to infections and pre-terms (NHS, 2012).

RTF is the only sterile liquid milk feeding in this NICU and it has three types which are P20/IF, P22, and P24. These RTF are special for growing, low birth weight infants and premature infants (Similac, 2022). According to the observations in this NICU, the RTF P20 is given to infants born more than 34 weeks (gestational age) and 2.5 kg bodyweight. The RTF P22 is special for infants born at 32 to 34 weeks (gestational age) and 1.7 kg to 2.5 kg and aged until 12 months. RTF P24 is given to infants born less than 34 weeks (gestational age), below 1.0 kg bodyweight and age until 3 months.

According to CDC (2022a), RTF is a sterile liquid infant formula that is ready to feed without water added and is safe to be consumed than PIF. Therefore, RTF is identified as non-SRM because it is sterile milk and free from bacteria. Certificate of analysis (COA) of these RTF from a supplier can be a preventive measure to confirm that the milk is safe from any hazards. RTF is sterile milk with aseptic packaging (shelf stable) until it is opened. RTF milk undergoes a sterilisation process (ultra-heat temperature with 135 °C (2-5 s) (Montagne *et al.,* 2009). According to BDA (2016), the unopened RTF is free from microbiological contamination.

Milk supplements

Milk supplements in this NICU consist of human milk fortifier (HMF), protein powder, medium-chain triglyceride (MCT) oil and Carborie. Premature and sick infants in the NICU require a lot of nutrients during hospitalisation and receiving nutrients from breast milk is inadequate even if it is the best feeding (Amissah *et al.,* 2018a). Fortification of breast milk with nutrient is necessary to avoid nutrient deficiencies among premature infants. HMF, protein powder, MCT oil and Carborie are nutritional supplements that were commonly used during fortification of milk. These supplements are added after warming the milk feeding.

HMF contains extra calories, vitamins and minerals for premature and low birth weight infants (Lin *et al.,* 2022). It helps to increase the nutrients in milk for infant's body weightt and growth (Verma & Yadav, 2018). Based on peer-reviewed study, the HMF used in this NICU can preserve the antibacterial activity of human milk against *E. coli, Staphylococcus,* Group B *Streptococcus* and *C. sakazakii* (Chan, 2003). MCT oil is a saturated fat from coconut or palm oil and helps to increase fat absorption and is suitable for infants with very low birthweight (VLBW) (Yamada *et al.,* 1988).

Carborie is a supplement from maltodextrin (corn) that provides additional calories from carbohydrates and promotes infant growth (Valens, 2022a). Carbohydrate supplements are fed to preterm infants after they start to consume breast milk (Mangili, 2007). Adding the Carborie to breast milk may help in increasing the carbohydrate level in milk. Meanwhile, protein powder (Myotein) has been added to breast milk to provide extra protein to infants. Myotein is a whey protein concentrate that is suitable to be used as a protein supplement to provide the addition of high-quality protein (Valens, 2022b). It is shown that protein supplementation of human milk increased head growth, length and weight gain among preterm infants (Amissah *et al.,* 2018b).

Certificate of analysis (COA) of these supplements from a manufacturer can be a preventive measure to control any hazards in the supplements and to ensure the supplements are safe for milk fortification. Supplements (HMF, protein powder, MCT oil and Carborie) in this NICU were identified as non-SRM.

Water

Water is used for reconstituted PIF in this NICU. *Pseudomonas aeruginosa* is a common pathogen found in water and surfaces in the NICU. This pathogen has been found in tap water that has been contaminated in the NICU (Bicking *et al.,* 2017). A water filter with a hole size of less than 0.5 µm can remove bacteria. *Pseudomonas* is a rod-shaped bacterium that is 0.5 to 0.8 µm in size and 1.5 to 3.0 µm. Therefore, submicron type water filters are needed for filtration. The use of water filters has been found to reduce *Pseudomonas* in the water of ICU wards (Trautmann *et al.,* 2008). The possible chemical hazards in water are pesticide residues, chlorine and heavy metals (EPA, 2021). However, these hazards were excluded because the filtered water was used for reconstituted milk. In addition, the filtered water was boiled before being used. Boiling water for 1 minute is the best method to kill bacteria, viruses, and parasites (CDC, 2022b). Therefore, water was identified as non-SRM.

CONCLUSION

The SRM in the milk room of the NICU were identified as DEBM, FEBM, EBMH and PIF milk. SRM must be handled very carefully with hygiene practices and stored at an appropriate temperature to avoid milk spoilage. The identification of SRM in the milk room will assist the NICU to control the significant hazards in the raw materials and prevent contamination of the final product. Thus, staff training on safe milk handling and storage temperature monitoring practices should be improved for the safety of milk feeding.

Table 1. Hazard analysis of raw materials

(1) **Raw material**	(2) Potential hazard B = Biology P = Physical C = Chemical	(3) Rationale for inclusion or exclusion as a Hazard	(4) Significance of Hazard L: Low, M: Medium, H: High Sev: Severity, Lik: Likelihood R: Risk, Sig: Significant				(5) Preventive measure	(6) Is this a sensitive raw material (SRM)? (Yes = Y; No = N)			
			Sev	Lik	R	Sig		Q1	Q2	Q3	SRM
a) Donor expressed breast milk (DEBM)	B: HIV, HTLV I or II, Hepatitis B or C, Syphilis, *Enterobacteriaceae* spp. such as *Pseudomonas aeruginosa, Klebsiella* and *Staphylococcus aureus* (NICE, 2010; Baumer 2004; PATH, 2016)	Inclusion: The donor is HIV, HTLV I or II, Hepatitis B or C, Syphilis positive.	M	H	M*H	Yes	Assessment test and serological test.	Y	Y	Y	Y
	P: hair (PATH, 2016)	Exclusion: Seldom occur and donor practices aseptic technique during expression.	-	-	-	-	-	-	-	-	-
	C: Nicotine (Hartmann *et al.,* 2007), drug (Liston, 1998), alcohol (NICE, 2010).	Inclusion: Donor is smoker and under nicotine replacement therapy (NRT), taking alcohol and drugs.	M	H	M*H	Yes	Assessment test and serological test.	Y	Y	Y	Y
b) Freshly expressed breast milk (FEBM)	B: *Enterobacteriaceae* spp. such as *Pseudomonas aeruginosa*, *Klebsiella* (Mahirah, 2022) and *Staphylococcus aureus*	Inclusion: Presence of Gram- negative bacteria *Enterobacteriaceae* spp. and Gram- positive cocci in breast milk.	M	H	M*H	Yes	Monitor expression technique. Ensure milk is stored immediately in the chiller. Microbiological test.	Y	N	-	Y
	P: none	-	-	-	-	-	-	-	-	-	-
	C: Lotion contains paraffin (Noti *et al.,* 2003)	Exclusion: Seldom occur.	-	-	-	-	-	-	-	-	-
c) Expressed breast milk (EBMH) (Expressed milk at home)	B: *Enterobacteriaceae* spp. such *as Pseudomonas, Klebsiella, Citrobacter freundii,* Gram-positive cocci, such as *Staphylococcus aureus* and *Enterococcus hirae.*	Inclusion: Presence of Gram- negative bacteria *Enterobacteriaceae* spp. and Gram- positive cocci in breast milk.	M	H	M*H	Yes	Bacterial in milk expressed at home can be reduced via pasteurization.	Y	Y	Y	Y
	P: hair	Exclusion: Mother practice hygiene practices during milk expression.	-	-	-	-	-	-	-	-	-
	C: Hand lotion contains paraffin (Noti *et al.,* 2003)	Exclusion: Seldom occur. Advice mothers to avoid using hand lotion contain paraffin.	-	-	-	-	-	-	-	-	-

Table 1. *Continued...*

d) Powdered infant milk (PIF)	B: Gram negative bacteria *Enterobacteriaceae* spp. such as*Cronobacter sakazakii*(Himelright *et al.,* 2002*, Citrobacter freundii*, and *Salmonella* spp. . (FAO/WHO, 2007a) and Gram-positive cocci, *Enterococcus hirae*.	Inclusion: *Cronobacter sakazakii* and *Salmonella* spp. in powdered infant formula.	M	H	M*H	Yes	Reconstitued milk with hot water at > 70°C (WHO 2007). Get letter of guarantee (LG) and Certificate of Analysis (CoA) from supplier.	Y	Y	Y	Y
	P: Plastic	Exclusion: Presence of plastic in milk can be monitored via visual monitoring during fortification.	-	-	-	-	-	-	-	-	-
	C: None	-				-	-	-	-	-	-
e) Ready to feed milk	B: None P: None C: None	Exclusion: RTF is sterile milk.	L	L	L*L	No	Check Certificate of Analysis (CoA) from supplier.	N	-	-	N
f) Supplement	B: Gram negative bacteria *Enterobacteriaceae* spp. such as *C. sakazakii* and *Salmonella* spp.	Exclusion: Presence of *C. sakazakii* and *Salmonella* can be assessed from (CoA) of supplier.	L	H	L*H	No	Check Certificate of Analysis (CoA) from supplier.	N	-	-	N
	P: None	-	-	-	-	-	-	-	-	-	-
	C: None	-	-	-	-	-	-	-	-	-	-
g) Water	B:	Exclusion: Water has been filtered and boiled.	L	L	L*L	No	Regular service and maintenance of water filter. Ensure to boil water for 1 min	N	-	-	N
	P: None	-	-	-	-	-	-	-	-	-	-
	C: Chlorine, pesticides	Exclusion: Water has been filtered	L	L	L*L	No	Regular service and maintenance of water filter.	N	-	-	N

Table 2. Hazard analysis of raw materials based on decision tree (MS 1480:2007)

Raw material	Decision tree			Is this raw material a sensitive raw material (SRM)? (Yes = Y; No = N)
	Q1 Is there a significant hazard with this raw material?	Q2 Are you or the consumer going to process this hazard out of this product?	Q3 Is there a cross-contamination risk to the fatality or to other products which will not be controlled?	
Donor expressed breast milk	Yes: If the donor is HIV, HTLV I or II, Hepatitis B or C, Syphilis positive.	Yes: Pasteurisation	Yes: Contamination may occur during milk storage and improper pasteurisation.	Yes
Expressed breast milk home	Yes: EBM is not sterile milk and	Yes: Pasteurisation	Yes: Contamination may occur during milk storage and improper pasteurisation.	Yes
Freshly expressed breast milk	Yes: EBM is not sterile milk with no heat treatment.	No.	-	Yes
Powdered infant formula milk	Yes: PIF is associated with *Cronobacter sakazakii* and *Salmonella* spp.	No.	-	Yes
Ready to feed milk	No: Ready to feed milk is sterile milk.	-	-	No
Supplement	No	No	-	No
Water	No	No	-	No

#HIV: Human Immunodeficiency Virus, HTLV: Human T-cell Lymphotropic Virus, EBM: Expressed Breast Milk, PIF: Powdered Infant Formula

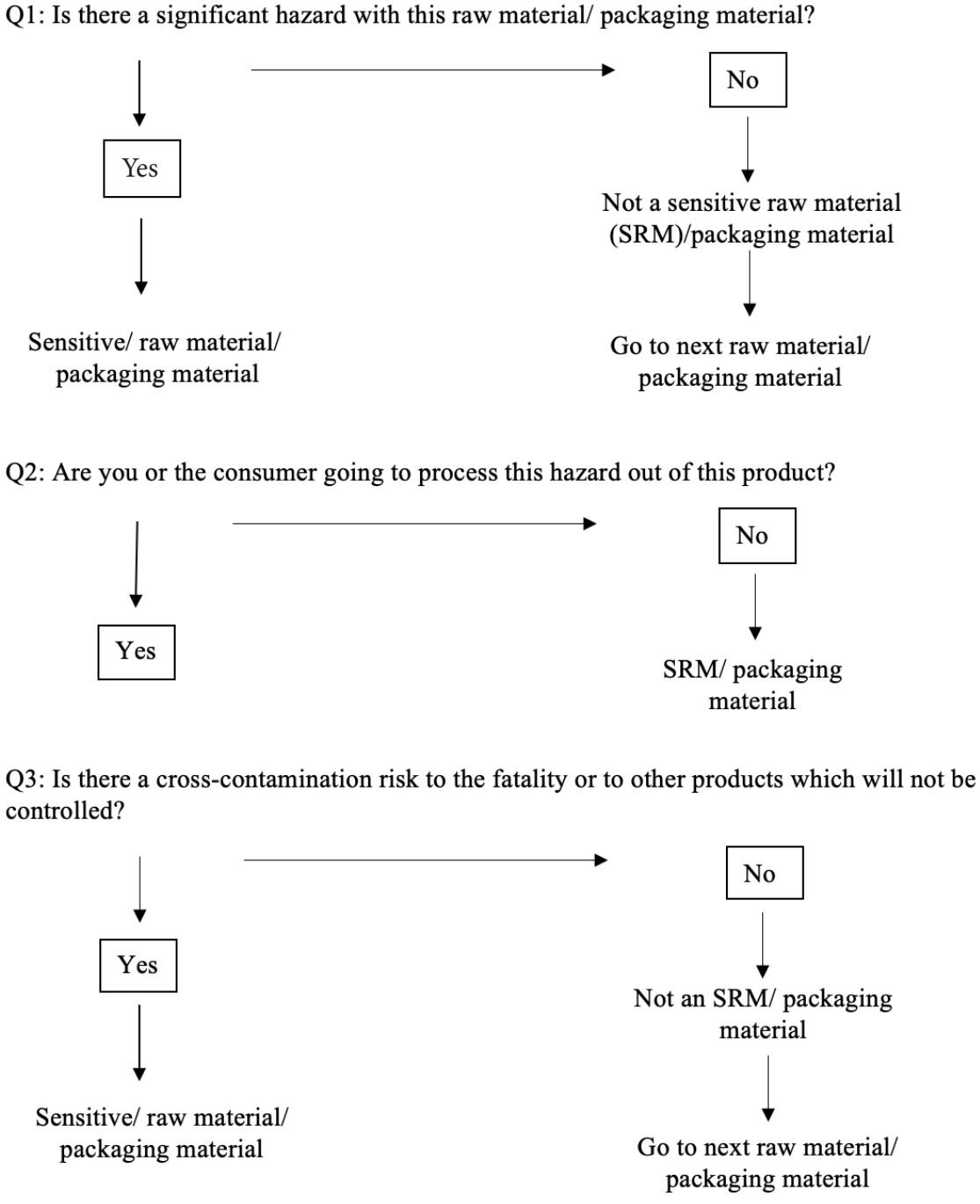

Fig. 1. Decision tree for raw material/ packaging material (MS 1480:2007)

ACKNOWLEDGEMENTS
This study was funded by the *Dana Impak Perdana* (DIP-2014-007), GP-K007337 and GP-2019-K010696 (01) of the Universiti Kebangsaan Malaysia.

ETHICAL STATEMENT
This study was approved by the Ethical Committee UKM 1.5.3.5/244/FST-2015-013.

CONFLICT OF INTEREST
The authors declare no conflict of interest.

REFERENCES
ADA. 2011. Infant feedings: Guidelines for preparation of human milk and formula in health care facilities. 2nd Ed. Pediatric Nutrition Practice Group, United States of America.

Almeida, R.C.C., Matos, C.O. & Almeida, P.F. 1999. Implementation of a HACCP system for on-site hospital preparation of infant formula. Food Control, 10: 181-187. https://doi.org/10.1016/S0956-7135(99)00016-X

American Academy of Pediatrics. 2012. Breastfeeding and the use of human milk. Pediatrics, 129(3): 827-841. https://doi.org/10.1542/peds.2011-3552

Amissah, E.A., Brown, J. & Harding, J.E. 2018a. Carbohydrate supplementation of human milk to promote growth in preterm infants. The Cochrane Database of Systematic Reviews, 8(8): CD000280.

Amissah, E.A., Brown, J. & Harding, J.E. 2018b. Protein supplementation of human milk for promoting growth in preterm infants. Cochrane Database of Systematic Reviews, 6(6): No. CD000433. https://doi.org/10.1002/14651858.CD000433.pub2

Angulo, F.J., Cahill, S.M., Wachsmuth, I.K., Costarrica, M.L. & Embarek, P.K.B. 2008. Powdered infant formula as a source of Salmonella infection in infants. Clinical Infectious Diseases, 46(2): 268-273. https://doi.org/10.1086/524737

Azevedo, I., Regalo, M., Mena, C., Almeida, G., Carneiro, L., Teixeira, P., Hogg, T. & Gibbs, P.A. 2005. Incidence of *Listeria* spp. in domestic refrigerators in Portugal. Food Control, 16: 121-124. https://doi.org/10.1016/j.foodcont.2003.12.006

Bankhead, R., Boullata, J., Brantley, S., Corkins, M., Guenter, P., Krenitsky, J., Lyman, B., Metheny, N.A., Mueller, C., Robbins, S. & Wessel, J. 2009. A.S.P.E.N. Board of Directors. Enteral nutrition practice recommendations. Journal of Parenteral and Enteral Nutrition, 33(2): 122-167. https://doi.org/10.1177/0148607108330314

Baumer, J.H. 2004. Guidelines for the establishment and operation of human milk banks in the UK. Archives of Disease in Childhood, 89(1): 27–28. https://doi.org/10.1136/adc.2004.053330

Best, C. 2008. Enteral tube feeding and infection control: how safe is our practice? The British Journal of Nursing, 17(1036): 1038-104l. https://doi.org/10.12968/bjon.2008.17.16.31069

Bicking, K.C., Koirala, S., Solomon, B., Rosenberg, J., Robinson, B.F., Neri, A., Laufer H.A., Arduino, M.J., Moulton-Meissner, H., Noble-Wang, J., Chea, N. & Gould, C.V. 2017. *Pseudomonas aeruginosa* outbreak in a neonatal intensive care unit attributed to hospital tap water. Infection Control and Hospital Epidemiology, 38(7): 801-808.

Boo, N.Y., Puah, C.H. & Lye, M.S. 2000. The role of expressed breastmilk and continuous positive airway pressure as predictors of survival in extremely low birthweight infants. Journal of Tropical Paediatric 46(1): 15-20.

Boo, N.Y., Nordiah, A.J. & Alfizah, H. 2001. Contamination of breast milk obtained by manual expression and breast pumps in mothers of very low birth weight. Journal of Hospital Infection, 49: 274–281. https://doi.org/10.1053/jhin.2001.1117

Bowen, A.B. & Braden, C.R. 2006. Invasive *Enterobacter sakazakii* disease in infants. Emerging Infectious Disease, 12(8): 1185–1189. https://doi.org/10.3201/eid1208.051509

Bowen, A., Wiesenfeld, H.C., Kloesz, J.L. 2017. Notes from the Field: *Cronobacter sakazakii* infection associated with feeding extrinsically contaminated expressed human milk to a premature infant — Pennsylvania. MMWR and Morbidity and Mortality Weekly Report 66(28): 761–762. https://doi.org/10.15585/mmwr.mm6628a5

BDA. 2016. Guidelines for the Preparation and Handling of Expressed and Donor Breast Milk and Special Feeds for Infants and Children in Neonatal and Paediatric Health Care Settings. United Kingdom: British Dietetic Association.

Brown, N.M., Arbon, J. & Redpath, C.2000. Contamination of milk bank samples with *Pseudomonas aeruginosa* during pasteurisation by penetration of organisms through the screw lid during cooling. Journal of Hospital Infection, 46:321–322.

CAC. 1997. Hazard Analysis and Critical Control Point (HACCP) system and guidelines. Codex Alimentarius Commission.

CAC. 2008. Code of hygienic practice for powdered formulae for infants and young children. CAC/RCP 66-2008. Codex Alimentarius Commission.

CDC. 1993. Centers for Disease Control and Prevention Salmonella serotype Tennessee in powdered milk products and infant formula - Canada and the United States, MMWR Morbidity and Mortality Weekly Report, 42: 516-517.

CDC. 2002a. How to prepare and store powdered infant formula during an emergency. https://www.cdc.gov/nutrition/emergencies-infant-feeding/powdered-infant-formula.html. (accessed 03.19.2023).

CDC. 2022b. Make water safe during an emergency. https://www.cdc.gov/healthywater/emergency/pdf/make-water-safe-during-emergency-p.pdf (accessed 08.18.2022).

Chan, G.M. 2003. Effects of powdered human milk fortifiers on the antibacterial actions of human milk. Journal of Perinatology, 23(8): 620-623. https://doi.org/10.1038/sj.jp.7211003
Chenu, J.W. & Cox, J.M. 2009. *Cronobacter* (‘*Enterobacter sakazakii*’): current status and future prospects. Letters in Applied Microbiology, 49: 153–159. https://doi.org/10.1111/j.1472-765X.2009.02651.x
Davidson, D.C., Poll, R.A. & Roberts, C. 1979. Bacteriological monitoring of unheated human milk. Archives of Disease in Childhood, 54(10): 760-764. https://doi.org/10.1136/adc.54.10.760
Donowitz, L.G., Marsik, F.J., Fisher, K.A. & Wenzel, R.P. 1981 Contaminated breast milk: A source of *Klebsiella bacteremia* in a newborn intensive care unit. Reviews of Infectious Diseases, 3(4): 716-720. https://doi.org/10.1093/clinids/3.4.716
EPA.2021. Types of Drinking Water Contaminants. https://www.epa.gov/ccl/types-drinking-watercontaminants#:~:text=These%20contaminants%20may%20be%20naturally,as%20microbes%20or%20microbiological%20contaminants (accessed 08.18.2022).
FAO. 1998. Food Quality and Safety Systems – A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System. Rome: Food and Agriculture Organization.
FAO/WHO. 2006. Food and Agriculture Organization of the United Nations/World Health Organization, *Enterobacter sakazakii* and *Salmonella* in powdered infant formula; meeting report. Microbiological Risk Assessment Series, pp. 10
FAO/WHO. 2007. Safe Preparation, Storage and Handling of Powdered Infant Formula Guidelines 1–26.http://www.who.int/foodsafety/publications/micro/pif2007/en/index.html (accessed 12.07.2016).
FAO. 1997. Food and Agriculture Organization of the United Nations. HACCP Principles & Application Guidelines. https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines (accessed 08.12.2022).
FAO/ WHO. 2008. *Enterobacter sakazakii* (*Cronobacter* spp.) in powdered follow-up formula. Meeting report. Rome, Italy. Food and Agriculture Organization.
Gad, S., Sheta, M.M., Al-Khalafawi, A.I., Abu El-Fadl, H.A., Anany, M., Sahmoud, S. & Amin, M.K. 2021. Expressed breast milk contamination in neonatal intensive care unit. Pediatric Health, Medicine and Therapeutics, 12: 307-313. https://doi.org/10.2147/PHMT.S311632
Gransden W, Webster, M., French, G.L. & Philips, I. 1986. An outbreak of *Serratia marcescens* transmitted by contaminated breast pumps in a special care baby unit. Journal of Hospital Infection, 7(2): 149-54. https://doi.org/10.1016/0195-6701(86)90057-5
Gras-Le Guen, C., Lepelletier, D., Debillon, T., Gournay, V., Espaze, E. & Roze, J. 2003. Contamination of a milk bank pasteurizer causing a *Pseudomonas aeruginosa* outbreak in a neonatal intensive care unit. Archives of Disease in Childhood-Fetal and Neonatal Edition, 88(5): 434-435. https://doi.org/10.1136/fn.88.5.F434
Haiden, N., Pimpel, B., Assadian, O., Binder, C., Kreissl, A., Repa, A., Thanhäuser, M., Roberts, C.D. & Berger, A. Comparison of bacterial counts in expressed breast milk following standard or strict infection control regimens in neonatal intensive care units: Compliance of mothers does matter. Journal of Hospital Infection, 92(3): 226–228. https://doi.org/10.1016/j.jhin.2015.11.018
Hartmann, B., Pang, W., Keil, A., Hartmann, P. & Simmer, K. 2007. Best practice guidelines for the operation of a donor human milk bank in an Australian NICU. Early Human Development, 83(10): 667–673. https://doi.org/10.1016/j.earlhumdev.2007.07.012
Himelright, L., Harris, E, Lorcg, V. & Anderson, M. 2002. *Enterobacter sakazakii* Infections associated with the use of powdered infant formula Tennessee. JAMA, 287(17): 2204–2205. https://doi.org/10.1001/jama.287.17.2204
HMBANA. 2020. HMBANA Standards for Donor Human Milk Banking: An Overview. Fort Worth, Texas: HMBANA.
HMBASA. 2011. Guidelines for the Operation of a Donor Human Milk Bank in South Africa. http://www.hmbasa.org.za/wp-content/uploads/2015/02/HMBASA-milk-bank-guidelines. pdf (accessed 08.04.2022).
Holy, O. & Forsythe, S. 2014. *Cronobacter* spp. as emerging causes of healthcare-associated infection. Journal of Hospital Infection, 86(3): 169–177. https://doi.org/10.1016/j.jhin.2013.09.011
Hunter, C.J. & Bean, J.F. 2013. *Cronobacter*: an emerging opportunistic pathogen associated with neonatal meningitis, sepsis and necrotizing enterocolitis. Journal of Perinatology, 33(8): 581–585. https://doi.org/10.1038/jp.2013.26
Jeurink, P.V., van Bergenhenegouwen, J., Jiménez, E., Knippels, L.M.J., Fernández, L., Garssen, J., Knol1, J., Rodríguez, J.M. & R. Martín.2013. Human milk: A source of more life than we imagine. Beneficial Microbes, 4(1): 17-30. https://doi.org/10.3920/BM2012.0040
Jones, C.A. 2001. Maternal transmission of infectious pathogens in breast milk. Journal of Paediatric and Child Health, 37:576-82
Kalyantanda, G., Shumyak, L. & Archibald, L.K. 2015. *Cronobacter* species contamination of powdered infant formula and the implications for neonatal health. Frontiers in Pediatrics, 3: 56. https://doi.org/10.3389/fped.2015.00056
Karimi, M., Eslami, Z., Lotfi, M.H., Nori, S., Zandi, H., Taghipour-Zahir, S. & Akhondzardaini, R. 2013. Bacterial contamination of expressed breast milk in neonatal intensive care unit. Zahedan Journal of Research in Medical Science, 15(4): 48-52.
Lataf, D.L.A., Mahyudin, N.A., Rashedi, I.F.M., Hariri, R. & Abdullah, A.Z. 2020. Hazard Analysis and Critical Control Point (CCP) determination in cook-chilled beef curry and beef kurma. Journal of Tourism, Hospitality and Culinary Arts, 12(1): 456-473.
Law, B.J., Urias, B.A., Lertzman, J., Robson, D. & Romance, L. 1989. Is ingestion of milk-associated bacteria by premature infants fed raw human milk controlled by routine bacteriologic screening? Journal of Clinical Microbiology, 27(7):1560-1566. https://doi.org/10.1128/jcm.27.7.1560-1566.1989
Liston, J. 1998. Breastfeeding and the use of recreational drugs-alcohol, caffeine, nicotine and marijuana.

Breastfeeding Review, 6(2): 27–30.
Lin, R., Shen, W., Wu, F., Mao, J., Liu, L., Chang, Y., Zhang, R., Ye, X., Qiu, Y., Ma, L., Cheng, R., Wu, H., Chen, D., Zheng, Z., Lin, X., Tong, X. & National Multicenter EUGR Collaborative Group. 2022. Human milk fortification in very preterm infants in China: A Multicenter Survey. Frontier in Pediatrics, (10): 795222. https://doi.org/10.3389/fped.2022.795222
Lucas, A., Cole, T.J., & Lucas, P.J. 1992. Breast milk and neonatal necrotising enterocolitis. Lancet, 339(8807): 1519-1523. https://doi.org/10.1016/0140-6736(90)93304-8
Mahirah, M. 2022. Pembangunan Sistem Keselamatan Makanan di Bilik Susu Unit Rawatan Rapi Neonatal (Ph.D). Universiti Kebangsaan Malaysia.
Malaysian Standard (MS 1480: 2007). Food safety according to Hazard Analysis and Critical Control Point (HACCP) system. Department of Standard Malaysia (First revision).
Mammina, C., Di Carlo, P., Cipolla, D., Casuccio, A., Tantillo, M., Plano, M.R., Mazzola, A. & Corsello, G. 2008. Nosocomial colonization due to imipenem-resistant *Pseudomonas aeruginosa* epidemiologically linked to breast milk feeding in a neonatal intensive care unit. Acta Pharmacologica Sinica, 29(12): 1486-1492. https://doi.org/10.1111/j.1745-7254.2008.00892.x
Mangili, G. & Garzoli, E. 2017. Feeding of preterm infants and fortification of breast milk. Pediatria Medica e Chirurgica [Medical and Surgical Pediatrics], 39(2): 62-66. https://doi.org/10.4081/pmc.2017.158
Mense, L., Rößler, S., Hanusch, R., Roßberg, C. & Rüdiger, M. 2014. Bacterial contamination of mechanically extracted breast milk. American Journal of Perinatology, 31(4): 293-8. https://doi.org/10.1055/s-0033-1348028
MOH. 2010. Garis panduan pensijilan HACCP Dapur Hospital Kerajaan. Kementerian Kesihatan Malaysia.
Mohd Bakri, J., Maarof, A.G. & Norazmir, M.N. 2017. Confusion determination of critical control point (CCP) via HACCP decision trees. International Food Research Journal, 24(2): 747-754.
Montagne, D. Van Dael, P., Skanderby, M., Hugelshofer, W., 2009. Infant formulae powders and liquids, dairy powders and concentrated products, In: Dairy Powders and Concentrated Products. A.Y. Tamine (Ed.). Wiley, Chichester. pp. 294-331.
Nakamura, K., Kaneko, M., Abe, Y., Yamamoto, N., Mori, H., Yoshida, A., Ohashi, K., Miura, S., Yang, T.T., Momoi, N. & Kanemitsu, K. 2016. Outbreak of extended-spectrum β-lactamase-producing *Escherichia coli* transmitted through breast milk sharing in a neonatal intensive care unit. Journal of Hospital Infection, 92(1): 42-46. https://doi.org/10.1016/j.jhin.2015.05.002
NHS 2012. Guide to bottle feeding https://www.ouh.nhs.uk/maternity/feeding/documents/guide-to-bottle-feeding.pdf (accessed 07.27.2022).
NICE. 2010. Donor breast milk banks: the operation of donor milk bank services. NICE Clinical Guideline, 93. NHS, London.
Norrakiah, A.S., Masomeh, G., Salam, B.A., Kupusamy, U.P. & Norizan, J. 2014. Incidence of *Cronobacter sakazakii* in powdered infant formula milk available in Malaysia. Sains Malaysiana, 43(12): 1855-1863.
Novak, F.R., Das, A.V., Hagler, A.N. & Figueiredo, A.M.S. 2000. Contamination of expressed human breast milk with an epidemic multi-resistant *Staphylococcus aureus* clone. Journal of Medical Microbiology, 49(12): 1109–1117. https://doi.org/10.1099/0022-1317-49-12-1109
Ogundele, M.O. 2000. Techniques for the storage of human breast milk: implications for anti-microbial functions and safety of stored milk. European Journal of Pediatrics, 159(11): 793-797. https://doi.org/10.1007/s004310000577.
Park, J., Seok, W., Choi, B.J., Kim, H., Lim, B.K., Yoon, S., Kim, S., Kim, Y., & Park, J.Y. 2004. *Salmonella enterica* serovar London infections associated with consumption of infant formula. Yonsei Medical Journal, 45 (1): 43-48. https://doi.org/10.3349/ymj.2004.45.1.43
PATH. 2016. Strengthening Human Milk Banking: A Workshop for Developing a Hazard Analysis and Critical Control Points Plan for Your Human Milk Bank – Trainee Workbook. USA: 1.1.
PATH. 2019. Strengthening Human Milk Banking: A Resources Toolkit for Establishing and Integrating Human Milk Bank Programs – A Training Curriculum Template for Hospital and Human Milk Bank Staff. Seattle, Washington, USA.
Perez, P.F., Doré, J., Leclerc, M., Levenez, F., Benyacoub, J., Serrant, P., Segura-Roggero, I., Schiffrin, E.J. & Donnet-Hughes, A. 2007. Bacterial imprinting of the neonatal immune system: lessons from maternal cells. Pediatrics, 119(3): 724-732. https://doi.org/10.1542/peds.2006-1649
Roberts, S. & Severn, M. 1978. Bacterial growth in raw and pasteurised human milk. British Medical Journal, 2(6146): 1196. https://doi.org/10.1136/bmj.2.6146.1196.
Rozolen, C.D., Goulart, A.L. & Kopelman, B.I. 2006. Is breast milk collected at home suitable for raw consumption by neonates in Brazilian public neonatal intensive care units? Journal of Human Lactation, 22(4): 418-425. https://doi.org/10.1177/0890334406293362
Rowe, B., Begg, N.T., Hutchinson, D.N., Dawkins, H.C., Gilbert, R.J., Jacob, M., Hales, B.H., Rae, F.A. & Jepson, M. 1987. *Salmonella ealing* infections associated with consumption of infant dried milk. Lancet, 2(8564): 900-903. https://doi.org/10.1016/s0140-6736(87)91384-5
Steel, C. & Short, R. 2008. Centralized Infant formula preparation room in the neonatal intensive care unit reduces incidence of microbial contamination. Journal of American Dietetic Association, 108(10): 1700-1703. https://doi.org/10.1016/j.jada.2008.07.009
Stevens, E.E., Patrick, T.E. & Pickler, R. 2009. A history of infant feeding. The Journal of Perinatal Education. 18(2): 32-39. https://doi.org/10.1624/105812409X426314
Trautmann, M., Halder, S., Hoegel, J., Royer, H. & Haller, M. 2008. Point-of-use water filtration reduces endemic *Pseudomonas aeruginosa* infections on a surgical intensive care unit. American Journal of Infection Control, 36(6): 421-429. https://doi.org/10.1016/j.ajic.2007.09.012
Threlfall, E.J., Ward, L.R., Hampton, M.D., Ridley, A.M., Rowe, B., Roberts, D., Gilbert, R.J., Van Someren, P., Wall, P.G. & Grimont, P. 1998. Molecular fingerprinting defines a strain of *Salmonella enterica* serotype

Anatum responsible for an international outbreak associated with formula-dried milk. Epidemiology and Infection, 121(2): 289-293. https://doi.org/10.1017/s0950268898001149

Turck D. 2012. Safety aspects in preparation and handling of infant food. Annals of Nutrition and Metabolism, 60: 211-214. https://doi.org/10.1159/000338215

Usera, M.A., Echeita, A., Aladueña, A., Blanco, M.C., Reymundo, R., Prieto, M.I., Tello, O., Cano, R., Herrera, D. & Martinez-Navarro, F.1996. Interregional foodborne salmonellosis outbreak due to powdered infant formula contaminated with lactose-fermenting *Salmonella virchow*. European Journal of Epidemiology, 12(4): 377-381. https://doi.org/10.1007/BF00145301

Valens. 2022a. Carborie. https://valensnutrition.com/product/carborie/ (accessed 08.22.2022).

Valens. 2022b. Myotein. https://valensnutrition.com/product/myotein/ (accessed 08.22.2022).

Verma, G., & Yadav, A. 2018. Role of human milk fortifier on weight gain in very low birth weight babies. International Journal of Contemporary Pediatrics, 5(2): 353-358. https://doi.org/10.18203/2349-3291.ijcp20180479

Wallace, A.W., Sperber, W.H. & Mortimores, S.E. 2011. Managing HACCP and Food Safety Throughout the Global Supply Chain. John Wiley & Sons, West Sussex. pp. 352.

Yamada, T., Nishida, H., Sakamoto, S., Okada, A., Sakanoue, M. & Suehiro, M. 1988. The effect of MCT oil suplement in very low birth weight infants, with evaluation by the 13c-labeled MCT breath test. Acta Paediatrica Japonica, 30(5): 564-568. https://doi.org/10.1111/j.1442-200x.1988.tb01581.x