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Failure Mode Effect Analysis (FMEA) At Good Manufacturing Practice (GMP) of Nata De Coco

C. Hari Wibowo[1], Berliana M.S.[2] , Yoyok B. Pramono[2]

[1]Semarang University, Faculty of Agricultural Technology
[2]Diponegoro University, Semarang, Faculty of Animal y and Agriculture Sciences, Food Technology Department.

Abstract:
Nata *de coco production* has a GMP aspect that needs to be implemented so that the production process can run well. The *Failure Mode and Effect Analysis* (FMEA) method is the stage of identifying the severity of product defects (*severity*), the incidence rate of product defects (*occurrence*), and the detection rate of product defects (*detection*), then calculating the *Risk Priority Number* (RPN) value, namely by multiplying the severity value (*severity*), the value of the event (*occurrence*), and detection value. *Nata* is a collection of cellulose with a chewy white texture that produces pieces of gel that float on the surface of the liquid. *Nata* is cellulose, the result of the synthesis of sugar in the form of agar by *Acetobacter xylinum*, which is white in color and contains about 98% water. The material observed was *Good Manufacturing Practice* (GMP) at *nata de coco* and observed how GMP was applied to locations, buildings, sanitation facilities, machinery and equipment, materials, process supervision, final products, laboratories, employees, packaging, product labels and descriptions, storage, maintenance, product recall and implementation of guidelines. The method used in calculating the observation results is *the Failure Mode Effect Analysis* (FMEA) method, the conclusion obtained is that the GMP score obtained in the manufacture of Nata de coco is less than optimal, which is 80 out of a total score of 100. FMEA obtained the results of problems that must be corrected immediately because they get a high RPN score, namely the *pasteurization, cooling,* drying, secondary packaging and storage of finished products Corrective actions and improvements need to be carried out immediately, especially in areas that receive high (critical) RPN scores, namely in the *pasteurization, cooling,* drying, secondary packaging and storage of finished products to avoid too many rejected products and product contamination. the lack of maximum GMP score can be identified as the source of the problem using the FMEA quantitative method. *Failure Mode Effect Analysis* (FMEA) is an effective *tool* in managing the potential for failure *(failure mode*), the results that arise from *the failure mode* and the level of criticality of the effect of the *failure mode* of the system of a product.

Keywords: FMEA, nata de coco, GMP

1. Introduction

A structured procedure to identify and prevent as many risks as possible that play a role in a failure through *a top-down* approach is the definition of *the Failure Mode Effect Analysis* (FMEA) method. *Failure Mode Effect Analysis* (FMEA) is an effective *tool* in managing the potential for failure (*failure mode*), the results that arise from *the failure mode* and the level of criticality of the effect of the *failure mode* of a product's system (Kartikasari *et al*., 2019). *Failure Mode Effect Analysis* (FMEA) can be used to find out the job, job description, failure mode, calculate *Risk Priority Number* (*Severity x Occurrence x Detection*) then get the highest RPN with this method, the company is expected to find a solution so that in the future the error can be corrected (Bastuti, 2020).

The GMP guidelines used as a reference are based on the Regulation of the Minister of Industry of the Republic of Indonesia No. 75/M-IND/PER/7/2010. The scope of GMP used in this analysis is the scope involved in the quality control process from the selection of raw materials to the packaging of the product. The scope of GMP in question amounts to 18, namely: location, building, sanitation facilities, machinery

and equipment, materials, process supervision, final products, laboratories, employees, packaging, product labels and descriptions, storage, maintenance and sanitation programs, transportation, documentation and recording, training, product recall and program implementation (Rini *et al.,* 2015).

The *Failure Mode and Effect Analysis* (FMEA) method is the stage of identifying the severity of product defects (*severity*), the incidence rate of product defects (*occurrence*), and the detection rate of product defects (*detection*), then calculating the *Risk Priority Number* (RPN) value, namely by multiplying the severity value (*severity*), the value of the event (*occurrence*), and detection value. After calculating the *Risk Priority Number* (RPN) value, the RPN value obtained from the result of multiplying the *severity, occurrence,* and *detection* values of each failure mode obtained and then sorting the largest to the smallest RPN value (Anastasya and Yuamita, 2022).

Nata is a collection of cellulose with a chewy white texture that produces pieces of gel that float on the surface of the liquid. *Nata* is cellulose, the result of the synthesis of sugar in the form of agar by *Acetobacter xylinum*, which is white in color and contains about 98% water. So far, the material that is often used as a medium for making nata is coconut water, known as *nata de coco* because of its complete nutritional content and suitable for bacterial growth (Utami *et al*., 2020). *Nata de coco* is cellulose which is the result of the activity *of Acetobacter xylinum*. In fact, nata is a layer of extracellular polysaccharides (*cellulose*) formed by the microbes that form the capsule. Nata is solid, white, clear, chewy, gel-like, and floats on the surface of the liquid. (Hamad *et al.*, 2014).

The purpose of this study is: to identify possible problems that can occur in each process using the *Failure Mode Effect Analysis* (FMEA) method, as well as to obtain knowledge related to studies in the field of food industry technology.

Materials and Methods

The material observed was *Good Manufacturing Practice* (GMP) *mini jelly* and *nata de coco* and observed how GMP was applied to locations, buildings, sanitation facilities, machinery and equipment, materials, process supervision, final products, laboratories, employees, packaging, product labels and descriptions, storage, maintenance, product recall and implementation of guidelines.

The method used in calculating the observation results is the *Failure Mode Effect Analysis* (FMEA) method. The first step in FMEA is to know and look for all possible modes of potential failure of a product or system. Then, a critical analysis is carried out on this failure mode taking into account the risk factors: event (O), severity (S), and detection (D). The purpose of the FMEA method is to prioritize the failure mode of the product or system to assign limited resources to the most serious risk items (Rizal *et al.,* 2022). The priority of the failure mode for corrective action is generally determined by the risk priority number (RPN), which is obtained by looking for the multiplication of O, S and D of a failure. RPN (*Risk Priority Number*) can be calculated using a mathematical formula (RPN= *Severity ´ Occurrence ´ Detection*) where O is the probability of failure, S is the severity of the failure, and D is the probability of failure not being detected. To obtain RPN from potential failure modes, the three risk factors were evaluated using a 10-point scale. The higher the RPN value of the failure mode, the greater the risk of product/system reliability. Failure modes can be sorted and the appropriate action will be selected on the high-risk failure mode (Sarinah and Djatna, 2015).

Results and Discussion

Failure Mode and Effect Analysis (FMEA) at *nata de coco Process*

The nata de coco *production process* starts from the storage of raw materials and packaging stored in the warehouse, this is done to prevent damage to raw materials and *packaging* or nata *de coco packaging.* In the second stage, there is a process of cooking *nata de coco* with a temperature of 98°C. In the third stage, there is a process of cooking syrup with a temperature of 98°C with a time of 12 minutes in this process, the syrup that is useful to be the flavor in *nata de coco* products is cooked or cooked. In the third stage, there is a *hot filling process* which is carried out at a minimum temperature of 85°C, at *this* hot feeling, *nata de coco* is put into the primary packaging. The fourth stage is the *sealing* process or sealing *of nata de coco products,* this sealing process is useful to prevent *nata de coco* from spilling so that it must be done properly

and correctly. The fifth stage is *pasteurization* at a temperature of 98°C for 25 to 30 minutes, in *this* pasteurization *process nata de coco* is soaked in hot water to kill all kinds of microorganisms to avoid contamination. The sixth stage is the cooling process with a temperature of 24 to 27 ° C with a time of 15 to 20 minutes, in the *cooling process the* nata de coco *product* is soaked in cold water to lower the temperature after the *pasteurization process* so that *the nata de coco* is not too cooked. The seventh stage is drying, this stage functions to dry *the nata de coco* from the remaining water in the *pasteurization* process and also *cooling*. The eighth stage is checking through *a metal detector*, this is done to avoid metal contamination in *nata de coco* packaging. The ninth stage is secondary packaging, this packaging is carried out to protect *nata de coco* from contamination and damage and facilitate distribution. The tenth stage, namely *nata de coco* that has been packaged and stored in the storage of finished products or finished product warehouses, this stage serves to keep the *finished nata de coco* product from being damaged before being distributed.

Tabel 1: *Failure Mode and Effect Analysis* (FMEA) at *nata de coco Process*

Process Step/Input	***Potential Failure Mode***	***Potential Failure Effects***	***SEVERITY* (1 - 10)**	***Potential Causes***	***OCCURRENCE* (1 - 10)**	***Current Controls***	***DETECTION* (1 - 10)**	**RPN**
	Possible failures that occur	The impact of failure		Causes of failure		Current failure prevention efforts		
Raw Material Storage and Packaging	Packaging of damaged raw materials g	Contaminate d materials	8	Pests, dust, dirt get into the storage area	6	Controlling by QC and warehouse	3	144
	Packaging damaged/torn	*Packaging* cannot be used	6	Damage during distribution to the machine	5	Control by QC	2	60
	Contaminatio n (dust and pests)	Contaminate d materials and *packaging*	9	Perforated and not yet *epoxy floors*	7	Manual sanitati on	4	252
NDC cooking (98oC)	Low pH	Batch fails and is discarded	9	Errors in NDC cooking	3	pH standard checking by process QC	4	108
	Less temperature	Batch fails and is discarded	9	Damaged steam jacket or leaking steam pipes and steam traps not	3	Control by QC	4	108

Based on Table 1. the *nata de coco production process* that has a high or critical score on the RPN value, namely *pasteurization*, *cooling*, drying, secondary packaging, and storage of finished products. In the storage of finished products, there is a possibility of contamination failures (dust and pests) that can result in contaminated raw materials and packaging , this is due to a perforated floor and has not *yet been epoxy*,

corrective actions can be taken in the form of repairing perforated floors and *epoxy* the floor for storing raw materials and *packaging*. In the *pasteurization* process, there is a possibility that *the pasteurization* failure is not maximized, this possibility can cause the nata to go stale before touching the expiration date, this can be caused by the *pasteurization* temperature is not hot and *the jelly* is not completely submerged, corrective actions can be taken in the form of improving *the pasteurization* heaterand the assignment of employees to ensure that all NATA is submerged on the *pasteurization* machine.

In the *cooling* process, there is a possibility of cooling failure that is not optimal, this possibility can cause nata *to be overcooked* and the texture of *nata* is not standard, this can be caused by a low temperature and *nata* is not submerged, corrective action can be taken in the form of repairing *the cooling* machine coolerand the assignment of employees to ensure that all NATA is submerged in *the cooling* machine. In the drying process, there is a possibility of failure of moist packaging, this possibility can cause moldy products, this can be caused by drying products that are still manual, corrective actions can be taken in the form of manual drying added with automatic drying.

In the secondary packaging process, there is a possibility of dirty packaging failure, this possibility can cause dusty products, this can be caused by the floor of the packaging room that is hollow and not yet *epoxy*, corrective actions can be taken in the form of repairing the floor of the packaging room and *epoxy the floor of the* packaging room. In the process of storing finished products, there is a possibility of failure that the temperature of the storage room is too high, this possibility can cause *the shelf life* of the product to be reduced, this can be caused by the building structure tending to absorb heat and poor air circulation, corrective actions can be taken in the form of replacing the roof of the storage room with a ceramic roof that is more heat-absorbing or adding ventilation to the storage room so that air circulation is better. Another possibility of failure in the finished product storage process is the presence of pests, this possibility can cause perforated products and the potential for product contamination, this can be caused by perforated storage room walls, corrective actions can be taken in the form of repairing perforated walls for storing finished products.

Conclusion

The GMP score obtained in the manufacture of Nata de coco was less than optimal, which was 80 out of a total score of 100. FMEA obtained the results of problems that must be corrected immediately because they get high RPN scores, namely the pasteurization process , *cooling,* drying, secondary packaging and storage of finished products.

Corrective and corrective actions need to be taken immediately, especially in areas that receive high (critical) RPN scores, namely in the *pasteurization, cooling,* drying, secondary packaging and storage of finished products to avoid too many rejected products and product contamination.

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Author Profile

C. Hari Wibowo Lecture in the Semarang University, Faculty of Agricultural TechnologyHis undergraduate degree was obtained from the Faculty of Animal and Agriculture Science Diponegoro University. The Master degree was obtained from Gadjah Mada University.

Berliana M.S. was accepted as a student in the Study Program Food Technology, Diponegoro University in 2020.

Dr. Yoyok Budi Pramono Lecture in the Food Technology study program at DiponegoroUniversity. His undergraduate degree was obtained from the Faculty of Animal and Agriculture Science. The Master degree and the Doctoral degree was obtained from Gadjah Mada University. He focuses on functional food science. He was published many of booksand scientific works have been published in Scopus and Sinta-Indexed journals.