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GMP Risk Assessment at an Organic and Natural Food Production Plant with Emphasis on Infrastructure by PHA and FMEA Methods

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ABSTRACT

In this new and applied study, the risks related to the possible states of pollution in GMP (Good Manufacturing Practices) in an organic and natural food production plant were investigated along with their risk factors and consequences and effects. Also, preventive and control measures were suggested to decrease the effects of risks. Also, the risk numbers prior and post preventive measures were calculated. To do so, the two FMEA and PHA methods were used. It was revealed that after the controlling measures, the risk numbers were decreased (in both methods) which is due to a decrease in the probability of occurrence. It is indicative of the effectiveness and fitness of all the suggested control measures.

Keywords: *FMEA, PHA, GMP, organic food products*

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1. INTRODUCTION

The risk assessment is the process of identification of the risks, a procedure, or a job and then, calculation of its risk index and finally, the provision of proper corrective solutions to control them (Total, 2004). The risk is the ability of a factor to produce a specific type of damage (ACDP, 1996). The probability of actuality of danger is called the risk. The description of risk is highly related to the probability of it (Dupont and Theodore, 2012). The risk is the probability of occurrence of danger and its severity, which leads to damage. In this regard, the risk does not have a fixed quantity and it is constantly changing (Muhlbauer, 1999).

There are different ways to assess the risk such as FMEA (Failure Modes and Effects Analysis) and PHA.

FMEA is a quite subjective systematic and preventive method which is used in definition, identification, assessment, prevention, omission, or controlling of the modes, causes, and effects of the potential errors in a system, process, plan, or service, and its condition is the prediction of the failures and the ways to prevent them (Krouwer, 2004; Gressel and Gideon, 1991; Cody, 2006).

The PHA method is used to identify the potential dangers in the preconstruction phases of industrial projects whose prerequisite is the preparation of a list of different dangers (Mohammad Fam, 2008).

To conduct the study in the PHA method, it is required to fully recognize the process production objectives, the environment in which the product is going to be produced, the equipment and hardware which are used along with the product and the operational criteria for the final consumer (Halvani and Zare, 2009).

The natural and organic food production plant is among the factories in which the GMP risk management related to different modes of pollution in its GMP process, based on the infrastructures, has not been investigated so far. This new and applied study deals with the risk assessment of the probable pollution modes in the GMP process in an organic food production plant through FMEA and PHA methods as well as the investigation of the risk factors and effects and consequences along with the preventive and control measures to reduce the risks.

2. METHODS:

FMEA:

The intensity of each of the risks is expressed based on Table 1 (defect intensity). The criterion for selection of the intensity index is determined based on the highest frequency. The obtained results in the intensity column (S) would be added to the risks analysis record sheet. Then, the occurrence of this incident would be determined based on Table 2, accordingly. These data also would be recorded in the risk analysis form.

Table 1: risk intensity (defect)

degree	Intensity (S)
1	trivial
2	low
3	serious
4	Critical
5	Disastrous

Table 2: risk occurrence probability

Row	Occurrence
1	Impossible
2	Unlikely
3	Sometimes
4	Probable
5	Repetitive

The risk index which is abbreviated as RIN is obtained from the multiplication of defect effect intensity (S) by the defect occurrence probability (O) which should be compared to the allowed rate of risk as shown in Table 3 (5).

$$RIN = S \times O \quad (1)$$

Table 3: risk matrix

			Intensity				
			Trivial	Low	Serious	Critical	Disastrous
			1	2	3	4	5
Occurrence probability	Impossible	1	1	2	3	4	5
	Unlikely	2	2	4	6	8	10
	Sometimes	3	3	6	9	12	15
	Probable	4	4	8	12	16	20
	Repetitive	5	5	10	15	20	25

The acceptable risks have a value of lower than 5. The reason behind this choice is the sensitivity of the organic food products to pollution. In case the calculated risk index is lower than the acceptable index, the risk would be acceptable and in case it is above this value, the risk is not acceptable and corrective or preventive and control measures must be taken to eliminate or reduce the risks, and afterward, the controlling measures must continue until the risk analysis group consider the risk rate to be acceptable.

PHA Method:

Table 4: risk analysis matrix for PHA method

Trivial (4)	Marginal (3)	Critical (2)	Disastrous(1)	risk intensity / occurrence probability
4A	3A	2A	1A	Repetitive(A)
4B	3B	2B	1B	Probable(B)
4C	3C	2C	1C	Sometimes(C)
4D	3D	2D	1D	Very low(D)
4E	3E	2E	1E	Unlikely(E)

Table 5: the concepts of risk criteria for different levels of risk by PHA method

Risk classification	Risk criterion
1A, 1B, 1C, 2A, 2B, 3A	Unacceptable
1D, 2C, 2D, 3B, 3C	Undesirable
1E, 2E, 3D, 3E, 4A, 4B	Acceptable but needs revision
4C, 4D, 4E	Acceptable and does not need revision

3. RESULTS AND DISCUSSIONS:

The risk assessment by the FMEA method is shown in Table 6.

Table 6: Risk assessment by the FMEA method

A risk assessment by the FMEA method										
Row	Hazard mode	Effect	Cause of occurrence	Probability (O)	Intensity (S)	Multiplication	Controlling measures	Probability (O)	Intensity (S)	Multiplication
1	The entrance of dust to the plant	Product's pollution	Generation of dust around the plant	2	4	8	The access points to the plant must be covered by a proper and resistant cover to prevent the generation of dust	1	4	4
2	Transmission of pollution caused by waste	Pollution of the internal space of the plant	Pollution caused by waste	2	3	6	Disposal of waste in containers with door	1	3	3
3	Pollution of the plant surroundings	Transmission of the pollution to the production halls	Inappropriate drainage of sewage on the road, street and factory parking	2	3	6	Existence of drainage of sewage on the road, street and factory parking	1	3	3
4	Lack of absorption of pollution by the vegetation	Transmission of the pollution to the internal production space	Shortage of green area around the plant and damaging this area	2	3	6	Appropriate protection of the plants and green area in the yard	1	3	3
5	Transmission of severe to the factory	Pollution of the raw, semi-processed, and final products	Lack of preventive measures against the local pollution (storm, flood, …)	2	4	8	Appropriate and effective measures against potential local pollutions	1	4	4
6	Increase in production space pollution	Probability of the semi-processed	Cleaning and maintenance equipment is not	2	4	8	Access to cleaning and maintenance equipment	1	4	4

		and final product pollution	available							
7	Transmission of pollution to the production halls	Probability of transmission of pollution to the semi-processed and final product	There are not any two-stage doors between the clean and unclean areas. There is no semi-clean area	2	4	8	Existence of a two-stage/automatic door (electronic or slow-closing) between the clean and unclean areas	1	4	4
8	Pollution of production space	Pollution of the final product	Insect and pest entry from entrances	2	4	8	Existence of air curtain	1	4	4
9	Increase in pests	Pollution of the production space and the final product	There are not enough pesticides	2	4	8	Measures needed for controlling the pest such as the installation of insecticides	1	4	4
10	Production hall pollution	Probability of pollution of the final product	The surface material is not appropriate for cleaning and absorbs pollution	2	4	8	The appropriateness of the floor, roof, and wall materials in a way it is resistant, smooth, impermeable, cleansable, and washable and stabilizable in case needed	1	4	4
11	Pollution of the production space and lines	Probability of transmission of pollution to the final product	The production hall floor does not have a slope and the water and pollution can be gathered there	2	4	8	The floor must have a slope in a way that it is inclined towards the canals	1	4	4
12	Production space pollution	Pollution of the final product	The exit of contaminants from sewage seams and drains	2	4	8	Sealing and drainage of the floor with lid and cover in wet process areas	1	4	4
13	Accumulation of pollution	Transmission of the pollution to the production hall	A 90-degree angle between the wall and floor which is a good place for accumulation of pollution	2	3	6	Roundness or open angles at the floor and wall-to-wall joints	1	3	3
14	Probability of chemical or biological reactions	Pollution of the production space	Mixing of the chemical and microbial pollutions	2	3	6	Existence of separate chemical and microbiological laboratories	1	3	3
15	Transmission and relocation of microbial pollution to the production space	Contamination of semi-processed and final products production lines	Lack of suitable microbiological hood or isolation chamber with UV lamp	2	4	8	Existence of suitable microbiological hood or isolation chamber with UV lamp	1	4	4
16	Damage to the production hall	Damage to the final product	Lack of proper control in sudden firers	2	4	8	Existence of fire alarm and extinguishing systems	1	4	4
17	Transmission of pollution to the internal production space	Possibility of transmission of pollution to the final product	Improper disposal of chemical and microbial wastes	2	4	8	Existence of hygienic and proper waste disposal system (chemical and microbial)	1	4	4
18	Production line pollution	Transmission of the pollution to the product	Water pollution and lack of regular periodic monitoring	2	4	8	Periodic water quality control and compliance with relevant standards	1	4	4
19	Transmission of the pollution to the product	The un-usability of the product	The material of water pipes in contact with the product is not suitable and they cannot be disinfected.	2	4	8	making the water pipes in contact with the product disinfectable	1	4	4
20	Lack of proper control over the operating conditions of the production process	Reduction in quality of the end product	Lack of proper control of temperature and humidity in the hall	2	4	8	The use of efficient and appropriate heating and cooling systems in the production halls	1	4	4

21	Production space pollution	Pollution of the final product	Pollution of the hall's air and lack of control	2	4	8	Existence of air purification systems	1	4	4
22	Pollution of production space due to leakage of air compressor oil	Possibility of pollution of semi-processed materials and the final product	Pollution caused by air compressor oil	2	4	8	Using oil-free compressors	1	4	4
23	Production lines pollution	Product pollution	Pollution of the production space due to the transfer of pollution from the sewage to it	2	4	8	No drainage beside the production lines	1	4	4
24	Microbial and biological pollution of production space	Contamination of semi-processed materials and the final product	Waste Pollution in Production Hall	2	4	8	Lack of waste in production halls	1	4	4
25	Microbial and biological pollution of production space	Contamination of semi-processed materials and the final product	Lack of covering of hazardous waste and materials	2	4	8	Existence of waste storage and hazardous materials tanks	1	4	4
26	Pollution of the production hall	Contamination of semi-processed materials and the final product	Creation of pollution through the holes and pores of the floor of the hall	2	4	8	Sealing of the holes and drainage	1	4	4

Determination of risk levels prior and post controlling measures are also shown in table 7 (based on the PHA Method).

Table 7: determination of risk levels prior and post control measures based on the PHA Method

PHA		
Row	Risk level	Risk level post controlling measures
1	2D	2E
2	3D	3E
3	3D	3E
4	3D	3E
5	2D	2E
6	2D	2E
7	2D	2E
8	2D	2E
9	2D	2E
10	2D	2E
11	2D	2E
12	2D	2E
13	3D	3E
14	3D	3E
15	2D	2E
16	2D	2E
17	2D	2E
18	2D	2E
19	2D	2E
20	2D	2E
21	2D	2E
22	2D	2E
23	2D	2E
24	2D	2E
25	2D	2E
26	2D	2E

Based on Table (6), 26 different risks were identified and their causes along with their consequences and effects were determined. Also, through the calculation of the risk indices, it was revealed that all 26 items needed preventive and controlling measures (risk indices above 5). The risk indices calculated by the use of FMEA Method had values of 6 and 8 (before control measures). The cases in which the risk index was 8 were those related to risks that lead to direct pollution of the final products and semi-processed materials. And the cases in which the risk index was 6 were those related to risks of pollution of the halls, especially the production hall. Also, this table shows that through controlling measures in designing the intended factory and its infrastructure (GMP), the risk indices can be lowered to 3 and 4.

The circular diagram (figure 1) of the FMEA table has been drawn. This diagram shows that 80.77% of the risks are those with critical intensity and unlikely occurrence probability (risks that lead to the direct pollution of the product) and 19.23% of the risks are those with serious intensity and unlikely occurrence probability (the risks that merely lead to pollution of the halls, especially the production halls).

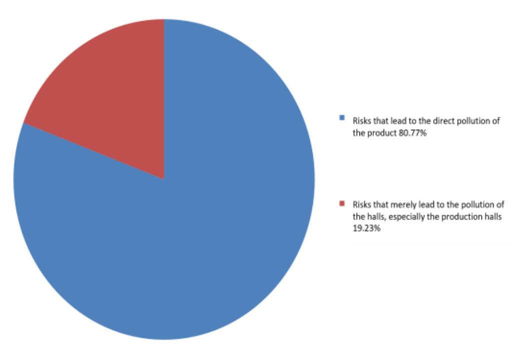

Figure 1: the circular diagram of the risks division for different modes of pollution

Table 7 shows the risk levels obtained by PHA Method. This table shows that from among a total of 26 identified risks that lead to the pollution of the product, 21 have 2D risk levels before the controlling and designing measures, which is reduced to 2E level post controlling measures. Also, the remaining 5 items have a risk level of 3D before controlling and designing measures, which is reduced to 3E after appropriate controlling measures. The comparison between the FMEA and PHA methods shows that FMEA is a quantitative and numerical method of risk assessment. Also, the PHA method is semi-quantitative. The FMEA method is much more suitable and better than the PHA method for the control and design phase.

4. CONCLUSIONS:

This study showed that Pay attention to the discussion of infrastructure in plant design is very necessary and important for preventing hazards. Also, it was showed that adhering to the GMP (good manufacturing practices) rules in design and construction to achieve optimal hygiene and cleanliness in the production environment and ultimately to achieve a high-quality product can help to a successful risk assessment. Also, FMEA is better that the PHA method for risk assessment in the design and preventive phase.

REFERENCES

1. Advisory Committee on Dangerous Pathogens (ACDP). (1996). Microbiological Risk Assessment: an interim report London: HMSO.
2. Cody, R. J. (2006). Anticipating risk for human subjects participating in clinical research: application of Failure Mode and Effects Analysis. *Cancer investigation*, *24*(2), 209-214.
3. Dupont, R. R., & Theodore, L. (2012). *Environmental health and hazard risk assessment: Principles and calculations*. CRC Press.
4. Gressel, M. G., & Gideon, J. A. (1991). An overview of process hazard evaluation techniques. *American Industrial Hygiene Association Journal*, *52*(4), 158-163.
5. Halvani, G.H., & Zare, M. (2009). *Safety System & Risk Management*. 1st ed. Tehran; Sobhan publication; 64-75.
6. Krouwer, J. S. (2004). An improved failure mode effects analysis for hospitals. *Archives of pathology & laboratory medicine*, *128*(6), 663-667.
7. Mohammad Fam I. (2008). *Safety Engineering*. Tehran; Fanavaran Publication; 35-40.
8. Muhlbauer, W. K. (1999). *Pipeline Risk Management Manual*, 2nd ed. Texas: Gulf Professional Publication; 428.
9. Total, E. L. F. (2004). Petroleum Iran. *HSE manual*.