ISSN 2083-1587; e-ISSN 2449-5999
2024,Vol. 28,No.1, pp. 23-35
Agricultural Engineering
www.wir.ptir.org
DOI: 10.2478/agriceng-2024-0003

THE USE OF THE DPMO INDICATOR TO VERIFY THE FULFILMENT OF HYGIENIC REQUIREMENTS IN THE FOOD INDUSTRY - A CASE STUDY

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ARTICLE INFO

Article history:
Received: September 2023
Received in the revised form: December 2023
Accepted: January 2024

Keywords:
DPMO Index,
food industry,
occupational hygiene

ABSTRACT

The quality of the manufactured product plays a special role in the food industry. Food producers, in addition to meeting consumer requirements, are obliged to comply with legally sanctioned, rigorous requirements of hygiene and cleanliness at work, as well as the way it is performed. In order to maintain the legally required hygiene rules in production plants specializing in the production of food products, manufacturers implement numerous management systems aimed at maintaining legally imposed guidelines in the field of quality management and occupational health. The article describes the use of the DPMO indicator, which allows for a thorough analysis of process parameters affecting the final quality of the manufactured product. For the analyzed process, the maximum DPMO value for one of the areas is 636364. In nine cases, which constitutes 12.5% of the total, DPMO is 0. The purpose of this article is to identify non-compliances in the field of occupational hygiene in the production plant analyzed using the DPMO indicator and then to introduce improvements. The developed recommendations concern marking, standardization and responsibility for individual processes as well as additional cleanliness inspections.

Introduction

The dynamically developing market, strong competition and high consumer demands force producers to take additional measures to ensure, apart from offering an attractive price of a product or service, also the appropriate quality of the goods offered. Everyone expects the food they eat to be clean, healthy, and safe to eat (Pal at al., 2016; Sharma et al., 2019). The quality of the manufactured product plays a special role in the food industry. Producers of food products, in addition to meeting consumer requirements, are obliged to comply with legally sanctioned, rigorous requirements of hygiene and cleanliness at work, as well as the way it is performed. Mandatory quality management systems in Poland and other EU countries are: GHP Good Hygienic Practice, GMP Good Manufacturing Practice as well as the Hazard Analysis and Critical Control Points System (Rosak-Szyrocka and Abbase, 2020). The most important EU and national legal acts on food safety from the point of view of the manufacturer of food products include, among others, Regulation of the European Parliament and of the EU Council 852/2004 of 29 April 2004 on hygiene of foodstuffs. Many legal acts specifying the requirements that are necessary to be met in order to produce and then place a food product on the market result from numerous threats, the occurrence of which may cause a potential threat to human health and, in extreme cases, to human life.

To maintain the legally required hygiene rules in production plants specializing in the production of food products, manufacturers implement numerous management systems aimed at maintaining legally imposed guidelines in the field of quality management and occupational health. The aforementioned systems are divided into those whose implementation is obligatory and results directly from legal requirements, e.g. Threat Analysis System and Critical Control Points (HACCP) and voluntary ones aimed at raising standards, which in turn are to lead to strengthening of the position of a given entity on the market by increasing competitiveness in terms of the quality of the goods offered (Wallace, 2014). The HACCP system is one of the best known and concerns a systematic approach to identification, assessment and control of the hazards during production, processing, production and preparation of food (Rosak-Szyrocka and Blažević, 2018; Kielesińska, 2018; Rosak-Szyrocka and Abbase, 2020).

The implementation of quality systems in the field of ensuring the required rules of occupational health and then maintaining the assumed standards in many casesis a key challenge for manufacturers. The personnel at the production level and those responsible for quality supervision should have appropriate qualifications and be familiar with the implemented quality assurance procedures in the production plant (Wrońska and Piepiórka-Stepuk, 2017; Wahyuni et al., 2019). Due to a high complexity of the systems and numerous documentations ensuring the maintenance of the implemented standards, an important role in maintaining the specified requirements is continuous control of the production process carried out in the form of cyclical internal audits. In most cases, audits are analytical in nature and their task is to obtain information whether the verified areas meet predefined requirements. Frequent internal audits allow for regular verification of the compliance with the established standards, which in the long term enables the identification of areas with the highest risk of non-compliance with previously established standards. One of the key decisive actions about the effectiveness of internal audits is the correct analysis of the information obtained. Qualitative tools and indicators can be used to analyze the data to identify the most common deviations from the accepted standards (Zhang et al., 2011). The purpose of this article is to identify non-compliances in the occupational hygiene in the production plant analyzed using the DPMO indicator and then introduce improvements.

DPMO Indicator

The variety of problems related to delays in the production process means that finding the answer regarding the occurrence of the causes and effects of the problems is not a simple task and requires some kind of systematization. For this purpose, quality management tools that allow for analysis and monitoring with a simultaneous impact on the process throughout the entire production cycle are used.

The key activity in the analysis of the results obtained in terms of the most common deviations from the accepted standards. The indicators based on the analysis of deviations from the theoretical state are DPU (Defects Per Unit - means the number of defects per unit), DPMO (Defects per Million Opportunities - means the number of defects per million possibilities of their creation) and DPO (Defects Per Opportunity - means the number of defects for all the possibility of their occurrence).

In the literature on the subject (Ismil et al., 2018; Ravichandran, 2018; Mustaniroh et al., 2021) the above-mentioned indicators are defined as a unit of quality measure or Six Sigma measure and described by the formulas 1-3.

$$DPU = \frac{D}{U} \tag{1}$$

$$DPMO = \frac{D*1{,}000{,}000}{U*0} \tag{2}$$

$$DPO = \frac{D}{U*0} \tag{3}$$

where:
D – deviations (defects)
U – units
O – possibility of defects per unit

The DPMO indicator, which was used in further analysis, is usually used in the Six Sigma methodology in the last stage of the DMAIC (Define, Measure, Analyze, Improve, Control) technique. The Control stage is to demonstrate that the changes introduced have reduced the number of defects (improved DPMO and raised the sigma level). This is done on account of the collected data from the process, which is analyzed using statistical methods.

The DPMO indicator is usually used to determine the possibility of a product defect in the case of high repeatability of its manufacture. It should be noted that the DPMO indicator allows not only to reflect the quality of the process or the manufactured product, but also allows you to compare the implementation of requirements of various complexity in many industries and services (Kamal and Parameaswari 2021; Coskun at al., 2016; Mondal at al., 2015; Mustaniroh et al., 2021). The fact that DPMO can be universally used to test the potential level of compliance with the assumed requirements has made it a commonly used measure for verification in terms of product quality analysis, but also compliance with the procedures for the correct implementation of process activities. The literature on the subject presents a number of examples describing the use of the DPMO indicator, which is usually used to analyze the quality of products during the production process or finished products (especially in production characterized by high repeatability), but also to analyze the effectiveness of services provided by companies from various industries (Setijono, 2009; Escobar and Morales-Menendez, 2018).

There is no information in the literature on the use of the DPMO indicator to analyze the results obtained based on internal audits, aimed at verification of the correct implementation of system activities.

In this article, by filling in the identified research gap, an analysis of data obtained from regularly conducted internal audits in a production company from the food industry was carried out. The analysis carried out aimed at identification of the areas where there is the greatest probability of non-compliance with the assumed standards in terms of such an important factor as compliance with hygiene in the implementation of production works. The obtained results may lead to the intensification of preventive measures ensuring additional protection of critical areas identified in the conducted analysis, using the DPMO indicator.

Methodology and case study

The tests were carried out in a food production plant located in Germany, which has a strict sanitary regime due to the specificity of the food industry and certification requirements - IFS Food Version 7.

The research covered the production preparation department, the boiler department, and the jar filling department, where jams and preserves production processes are carried out. Sanitary guidelines in force at the department concern both the cleanliness of the premises and production equipment as well as the hygiene of employees. The designated research area is crucial from the product perspective due to the presence of direct contact with the external environment before the jars are closed. Even the smallest mechanical or air contamination can lead to the formation of mold nuclei or to the ingress of foreign matter into the final product.

The research was conducted in four stages:

- stage I - identification of control areas - the aim of this stage was to brainstorm all potential research areas,
- stage II - selection of key research areas - the purpose of the stage was to select, using the index method, areas that are significant in terms of technology, organization and sanitary,
- stage III - inspections of selected areas at least once a day in terms of meeting sanitary requirements - the purpose of this stage was to collect data,
- stage IV - determination of the DPMO indicator according to the formula (1) for the following criteria: week, month, day of the week, hour, area - the purpose of this stage was to determine the indicators for comparative analysis. Presented in tab. 1-4 quantitative results were subjected to statistical analysis. For each criterion, a null hypothesis was put forward, stating that there would be significant differences in individual scales. The results of the probability of committing a type I error "p" are presented in each case below the tables. Due to the comparison of more than 2 scales of independent interval data, the Kruskal-Walis ANOVA test was used for analysis. 0.05 was assumed as α.

Results and Discussion

As part of stage I, 19 areas that could be controlled were identified by means of a brainstorming session involving three experts in the field of quality maintenance and production.

As part of stage II, experts awarded points from 0 to 10 for each of the areas indicated in stage I, specifying the importance of sanitary requirements for the production process. On the basis of the sum of the points awarded, 6 research areas were selected, which experts awarded the maximum number of points. These areas were:

– General order and cleanliness - boiler area (A),
– Cleanliness of the temperature-keeping container (B),
– Cleanliness of the vacuum boiler (C),
– General order and cleanliness of production (D),
– Personal hygiene of employees (E),
– Cleanliness of coiled hoses (F),
– Product traceability (G),
– Waste purity (H).

The above-mentioned selected areas within stage III were inspected on a daily basis over a period of 8 weeks. The inspections were carried out by two auditors, according to the established evaluation criteria. The obtained results were summarized on the Pareto chart (Fig. 1) and then the DPMO indicators presented in tables 1 and 2 were determined.

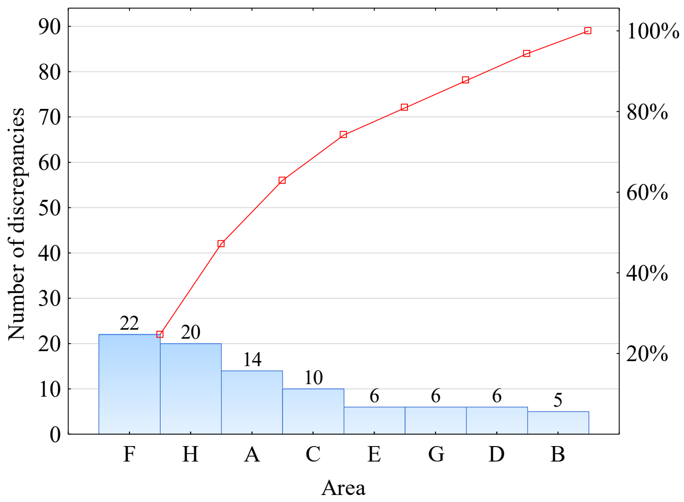

Figure 1. Pareto-Lorentz chart of identified discrepancies during the inspection

Table 1.
Values of the DPMO indicator for the controlled areas according to the day of the inspection week

Area	Day of the week				
	Monday	Tuesday	Wednesday	Thursday	Friday
A	181818	272727	363636	181818	300000
B	0	0	90909	181818	200000
C	181818	90909	272727	0	400000
D	90909	90909	181818	90909	100000
E	0	0	363636	90909	100000
F	454545	**636364**	363636	363636	200000
G	181818	90909	0	90909	200000
H	90909	**545455**	363636	272727	**500000**

p (day) = 0.270, p (area) = 0.011

Table 2.
Values of the DPMO indicator for the controlled areas due to the time of inspection

Area	Hour			
	6.00 a.m.-10.00 a.m.	10.01 a.m.-2.00 p.m.	6.00 a.m.	6.01 a.m.-7.00 a.m.
A	325000	71429	192308	571429
B	125000	0	153846	71429
C	225000	100000	269231	142857
D	100000	200000	115385	71429
E	150000	0	76923	285714
F	450000	400000	423077	**500000**
G	75000	300000	0	214286
H	350000	**600000**	384615	285714

p (hour) = 0.880, p (area) = 0.014

Based on the compiled list of results presented in Figure 1, it was found that among the selected areas subjected to verification, the largest number of non-conformities concerned the cleanliness of the coiled hoses (F) and the cleanliness of the drains (H). Inconsistencies in area (F) during internal audits were identified a total of twenty-two times, and in area (H) twenty times. The smallest number of Deviations from the set standards was reported in area B a total of five times, and in areas D,E,G six times.

Then, Tables 1 and 2 present data on the value of the DPMO indicator for the controlled areas, taking into account the assumed criterion, i.e. the day of the week and the time of identifying non-compliances. The analysis shows that the value of the DPMO indicator, which means the number of deviations (non-conformities) per million potential possibilities of their occurrence, was ≥500,000 for area (H) on Tuesday and Friday, while for area (F) only on Tuesday. In the case of the area concerning the cleanliness of drains, the value of the DMPO index was 600,000 between 10.01 a.m. and 2.00 p.m. when in the case of coiled hose purity, the DPMO index was 500,000 in the range of 6.01 a.m.-7.00 a.m. When analyzing the value of the DPMO indicator in terms of the number of deviations per million potentials for their creation, a high value of the indicator was also found in the range of 6.01 a.m.-7.00 a.m. for the area (A) amounting to 571429.

The highest value of the DPMO indicator was identified for the area (F) and amounted to 407,407, while the lowest value was recorded for area (B), i.e. 92,593.

The value of the DPMO indicator allows you to determine the Sigma levels of cleaning processes and determine its efficiency according to the adopted comparative criteria. Collectively, the Sigma level and the efficiency of the process for individual areas are shown in Figures 2 and 3. The Sigma levels of the process, due to the adopted comparative criteria, are presented in Table 3 and 4, and their efficiency in Figures 4 and 5.

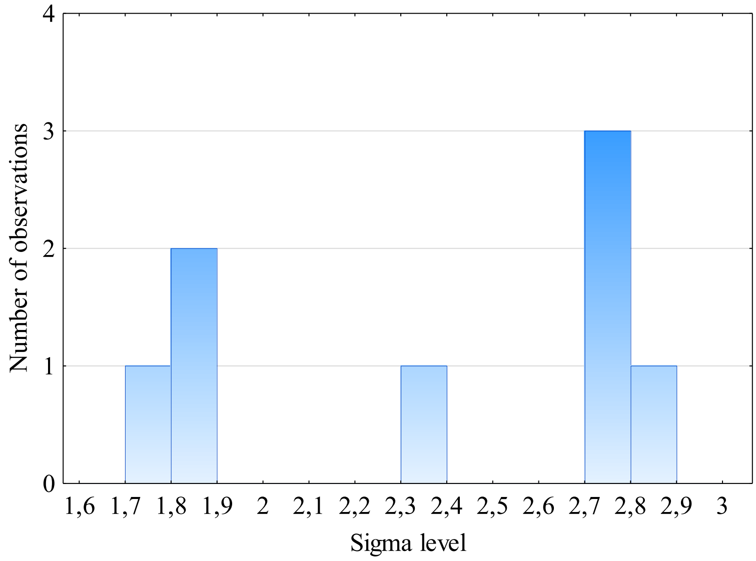

Figure 2. Sigma level of cleaning processes in the analyzed production areas

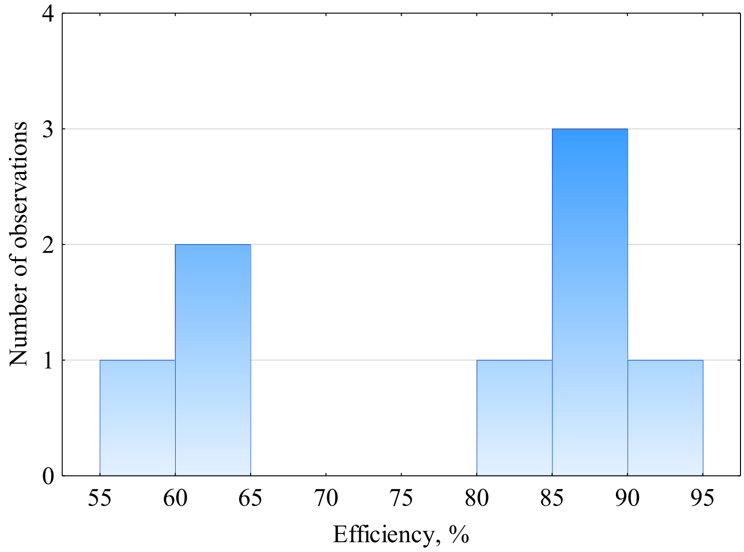

Figure 3. Efficiency of cleaning processes in the analyzed production areas

Table 3.
Sigma levels of cleaning processes for controlled areas by day of the week of control

Area	Day of the week				
	Monday	Tuesday	Wednesday	Thursday	Friday
A	2.41	2.10	1.85	2.41	2.02
B	39.97	39.97	2.84	2.41	2.34
C	2.41	2.84	2.10	39.37	1.75
D	2.84	2.84	2.41	2.84	2.78
E	39.97	39.97	1.85	2.84	2.78
F	1.61	1.15	1.85	1.85	2.34
G	2.41	2.84	39.97	2.84	2.34
H	2.84	1.39	1.85	2.10	1.50

p (day) = 0.275, p (area) = 0.010

Table 4.
Sigma levels of cleaning processes for controlled areas by inspection hour

Area	Hour			
	6.00 a.m.-10.00 a.m.	10.01 a.m.-2.00 p.m.	6.00 a.m.	6.01 a.m.-7.00 a.m.
A	1.95	2.97	2.37	1.32
B	2.65	39.97	2.52	2.97
C	2.26	2.78	2.12	2.57
D	2.78	2.34	2.70	2.97
E	2.54	39.97	2.92	2.07
F	1.63	1.75	1.69	1.50
G	2.94	2.02	39.97	2.29
H	1.86	1.25	1.79	2.07

p (hour) = 0.880, p (area) = 0.014

Based on the analysis of the sigma level of individual areas, it was found that, apart from a few areas where no deviations from the adopted standards were identified, the sigma level does not exceed the value of 2.9, which corresponds to the process efficiency of up to 95%. Taking into account that the food industry is analyzed, it was found that the efficiency of the cleaning process in the range of 55-95% is insufficient. When analyzing the cleaning in individual areas in the adopted comparative criteria, too large dispersion of efficiency was also found, in extreme cases below 40%.

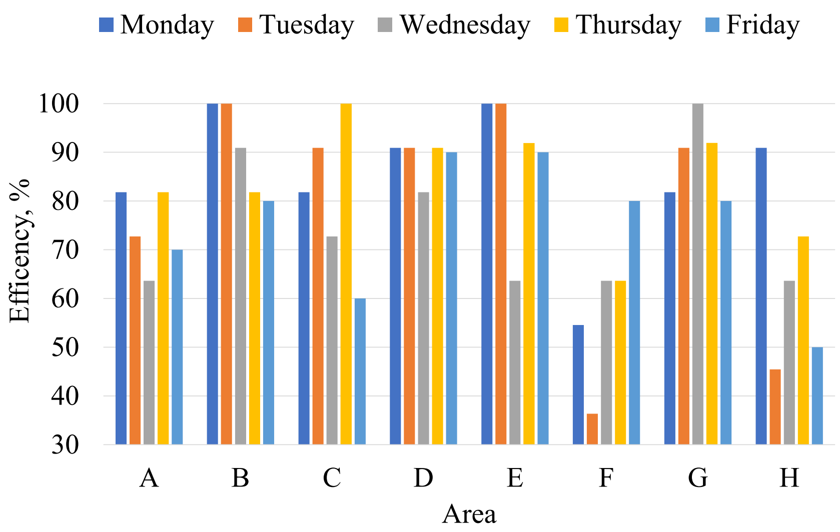

Figure 4. Efficiency of the cleaning process in the analyzed periods of the week

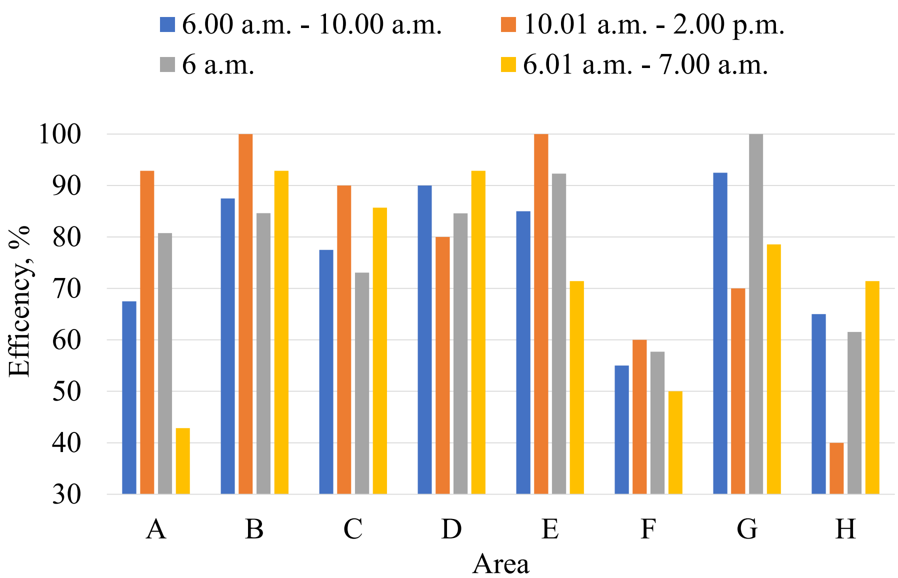

Figure 5. Efficiency of the cleaning process in the analyzed categories in the analyzed time periods

The obtained results made it possible to identify areas for which it is necessary to perform a series of analyzes aiming at identification of the causes of a large number of non-compliances, taking into account information on the time (day and time) when they were reported and then introduction of corrective actions. In connection with the above, a 3-person team consisting of representatives of the quality and production department was appointed to eliminate deviations and, consequently, to improve the stability of production in terms of quality.

The analysis of the obtained results allowed to confirm the thesis that the DPMO indicator can be useful for many industries. Similarly to the research results presented in the literature (Kamal and Parameaswari 2021; Coskun at al., 2016; Mondal at al., 2015; Mustaniroh et al., 2021), also in the case of the food industry and the identification of non-compliances for the key area of hygiene during production , the DPMO indicator allowed for determining the quality of the process according to the adopted comparative criteria. Since there is no information in the literature on the use of the DPMO indicator to analyze the results obtained on the basis of internal audits aimed at verifying the correct implementation of system activities, the presented results filled this research gap. It was confirmed that, according to (Zhang et al., 2011), quality indicators can be used to analyze data to identify the most common deviations from accepted standards in the food industry.

Voluntary analysis of process quality in the food industry in accordance with (Wallace, 2014) allows for raising standards, improving the quality of offered goods and meeting specific systemic hygiene requirements specified in HACCAP (Rosak-Szyrocka and Blažević, 2018; Kielesińska, 2018; Rosak-Szyrocka and Abbase, 2020). Actions taken in the area of reduction of non-compliances concerned, among others:

– Clear, unambiguous marking of areas where special care should be taken in terms of maintaining cleanliness. The marking consisted in placing pictogram arrows on the floor indicating the above-mentioned points.
– Introduction of standardized cleaning processes with direct responsibility for the area. Standardization of the cleaning process consisted in the introduction of instructions describing the method of removing dirt along with an indication of the frequency of activities and the development of a schedule. The implementation of the procedures was preceded by training for the staff. Each cleaning, in accordance with the developed schedule, is recorded by the cleaning person by means of an entry in the register developed for this purpose.
– Introduction of the principles of autonomous maintenance in areas F and H, in accordance with the principles of Lean Manufacturing, involving the implementation of related procedures with maintenance, cleaning and identification of potential non-compliances in the workplace. Autonomous maintenance, which is one of the pillars of TPM, involves the entire production staff in the effective use and maintenance of machines. It consists in transferring the simplest works and activities related to technical maintenance of devices from the maintenance department to the operators. In the analyzed case, the duties related to identifying the sources of emerging sanitary deviations and the self-control process, confirmed by an entry in the register, were transferred to the employees. The control is carried out on the basis of a checklist that is a part of the cleaning standard.
– Introduction of additional controls performed by shift managers in areas with the highest risk of non-compliance. The inspections carried out are conducted according to the "check

list" prepared by the quality department. Inspections verify the effectiveness of the autonomous maintenance (cleanliness) process. The inspection periods, apart from the standard daily inspections, consider the results of the analysis and the periods in which an increase in the number of deviations was recorded, indicated by the DPMO indicator. For example, for the "Drain cleanliness" (H) area, an additional four inspections have been designated, carried out each two on Tuesdays and Fridays from 10.01a.m.-2.00 p.m. with an interval of at least 2 hours.

Summary

The quality of the manufactured product plays a special role in the food industry. Food producers, in addition to meeting consumer requirements, are obliged to comply with legally sanctioned, rigorous requirements of hygiene and cleanliness at work, as well as the way it is performed. The growing awareness of the need to constantly improve the quality of products resulting from the increasing consumer awareness and the ever-increasing regulatory restrictions, imposed forces companies to implement new methods of analysis the processes used. In order to maintain the legally required hygiene rules in production plants specializing in the production of food products, manufacturers implement numerous management systems aimed at maintaining legally imposed guidelines in the field of quality management and occupational health.

The article describes the use of the DPMO indicator, which allows for a thorough analysis of process parameters affecting the final quality of the manufactured product. This is a continuation of activities resulting from internal audits customarily used in companies, which aim at identification of weaknesses and non-compliances. In the problem analyzed as a result, the use of the DPMO indicator made it possible to obtain results allowing for the identification of the areas characterized by the highest level of non-compliance.

As a result of their identification, changes were introduced to reduce or eliminate the causes of their formation. Based on the comparison of the DPMO results obtained before the introduction of improvements and after their implementation, it will be possible to assess the effectiveness of the implemented measures.

Acknowledgments

Silesian University of Technology (Faculty of Material Engineering, Department of Production Engineering) supported this work as a part of BKM-564/RM1/2023 (11/010/BKM23/0049).

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WYKORZYSTANIE WSKAŹNIKA DPMO W CELU WERYFIKACJI SPEŁNIENIA WYMOGÓW HIGIENICZNYCH W PRZEMYŚLE SPOŻYWCZYM – STUDIUM PRZYPADKU

Stresczenie. Jakość wyprodukowanych towarów spełnia bardzo istotną rolę w przemyśle spożywczym. Producenci żywności, oprócz spełnienia wymogów konsumenckich, są zobowiązani do przestrzegania prawnie usankcjonowanych, rygorystycznych wymagań dotyczących higieny i czystości w pracy oraz sposobu w jakim jest wykonywana. W celu zachowania wymaganych prawem zasad higieny w fabrykach produkcyjnych specjalizujących się w produkcji towarów spożywczych, producenci wdrażają liczne systemy zarządzania mające na celu przestrzeganie wytycznych w obszarze jakości zarządzania i bezpieczeństwa i higieny pracy. Niniejszy artykuł opisuje zastosowanie wskaźnika DPMO, który pozwala na dokładną analizę parametrów procesu, jakie wpływają na ostateczną jakość wyprodukowanych towarów. Dla analizowanego procesu, maksymalna wartość DPMO dla jednego z obszarów wynosi 636364. W dziewięciu przypadkach, które stanowią 12,5 % całości, DPMO wynosi 0. Celem niniejszego artykułu jest identyfikacja niezgodności w obszarze higieny i bezpieczeństwa pracy w fabryce przeanalizowanej za pomocą wskaźnika DPMO a następnie wprowadzenie ulepszeń. Opracowane zalecenia dotyczą oznaczania, standaryzacji oraz odpowiedzialności za indywidulane procesy oraz dodatkowych inspekcji czystości.

Słowa kluczowe: wskaźnik DPMO, przemysł spożywczy, bezpieczeństwo i higiena pracy