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Good Manufacturing Practices for Quality and Safety Management in the Food Industry

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Abstract. The article presents a description of the design and implementation of the FMEA methodology in a food company dealing with the processing of vegetables and fruits, where it is used in combination with the HACCP system as a tool for ensuring product quality and as a means of improving the operational efficiency of the production cycle. The use of the FMEA method as support for HACCP in terms of safety and quality allowed for step-by-step analysis of the production cycle, provided additional knowledge about processes and ultimately positively influenced both the process and the product itself.

Introduction

In today's world, the quality of food products is a key factor in a company's success. Customers are paying more attention to the composition and origin of products, so the food industry must adapt to their needs and expectations [1,2]. To achieve this, companies use various tools and quality management methods to ensure the safety and compliance of products with requirements. Quality is defined as the set of product characteristics that meet both stated and implied customer needs [3]. Adopting predefined standards enables Quality Assurance to provide customers with the assurance that the company is operating in accordance with these requirements. In the Food Industry, there are two distinct aspects of product quality: food safety and sanitary integrity, which are mandatory for selling food products, and other factors such as appearance, functionality, and nutritional characteristics that appeal to customers [4]. The use of Failure Mode and Effects Analysis (FMEA) methodology and incorporating its findings into an already established HACCP (Hazard Analysis and Critical Control Points) system allows for a comprehensive examination and analysis of both aspects of food quality. In the food industry, HACCP system is considered one of the good practices, other include [5, 6]:

- Quality control – a process of controlling the quality of products and services to ensure customer requirements are met.
- Proper identification and labelling of products – a process of identifying and labelling products, which allows for easy recognition of products and information about them.
- Cleanliness and sanitation – a process of maintaining cleanliness and sanitation to ensure food safety and the health of workers.
- Compliance with regulations and laws related to food safety, environmental protection and worker health.
- Employee training – training employees in food safety, compliance with regulations and good manufacturing practices.

- Monitoring and oversight – regular monitoring and oversight of production processes and food safety to ensure their effectiveness.

The HACCP system is counted among so called good practices in the food industry, and includes:

- Quality control – the process of controlling the quality of products and services to ensure that customer requirements are met.
- Correct product identification and labelling – the process of identifying and labelling products so that products and information about them can be easily identified.
- Cleanliness and sanitation – the process of maintaining cleanliness and sanitation to ensure food safety and employee health.
- Compliance with food safety, environmental and worker health laws and regulations.
- Worker training – training of workers in food safety, compliance with regulations and good production practices.
- Monitoring and supervision – regular monitoring and supervision of production processes and food safety to ensure their effectiveness.

Hazard Analysis and Critical Control Points (HACCP)

HACCP was first introduced to food service by the Minnesota Foodservice Quality Assurance program in 1974. The HACCP program can monitor food production from raw materials to end products and even as far as serving, based on controlling factors such as time, temperature, and specific factors that contribute to foodborne disease outbreaks.

End-point testing is not an effective way to guarantee food safety because by the time the results are available, the food has already been sent to the customer. A more effective approach is to implement additional procedures during the processing stage and monitor the process using a HACCP system, which has been shown to be a reliable method. HACCP is designed to prevent problems from occurring in the first place, rather than addressing them after they have happened. By following the guidelines of safe food production with the HACCP system, the risk of foodborne illnesses will be reduced. It should be emphasized that the HACCP system is a food supervision system and is aimed at eliminating direct causes of health risks, directly at the place of their origin. This system cannot be treated as a constant, once developed for a given facility procedure, including documents resulting from it [7]. The HACCP system should ensure food safety, through constant monitoring of biological, chemical and physical hazards in the process of production, storage and food distribution. Although the HACCP system is effective in ensuring food safety, it has several limitations, particularly for vegetable and fruit processing companies. One of the limitations of the HACCP system is limited effectiveness. The HACCP system is focused on identifying and controlling specific hazards, such as pathogenic bacteria, but does not take into account other potential problems, such as production errors. In the case of vegetable and fruit processing companies, this may lead to a lack of control over other hazards, such as chemical contamination or microbiological pollution. Another limitation is the dependence on the accuracy and reliability of the analysis [8, 9] The effectiveness of the HACCP system depends on the accuracy and reliability of the analysis of hazards, so it is important to conduct it in an appropriate and objective manner. In the case of vegetable and fruit processing companies, difficulties related to identifying all hazards may lead to a lack of effective control over product safety. HACCP focuses on identifying and controlling critical control points to prevent food safety hazards and ignores the aspect of production. In this case, the FMEA method, which focuses on identifying and assessing potential errors and their effects, is appropriate. The use of the FMEA method can help identify potential problems in the production process, allowing for preventative actions to be taken, which in turn can reduce the risk of food safety hazards. However, FMEA and HACCP are complementary methods and both should be used together to ensure the highest level of food safety.

Failure Mode and Effects Analysis (FMEA)

FMEA involves conducting a risk analysis for each stage of the production process, in order to identify potential errors and their effects. These analyses include criteria such as the frequency of error occurrence, its impact, and the level of difficulty in detecting it [12-14]. Based on these criteria, the risk of a given error is evaluated and preventive actions such as modifying the production process or adding quality control are taken. In the food industry, FMEA is particularly useful in identifying potential food safety hazards such as microorganisms, chemical contamination, or physical contamination. This analysis allows for the identification of potential sources of hazards and preventive actions such as changing the production process or adding quality control, which can reduce the risk of these hazards occurring. Furthermore, FMEA can also help in identifying potential issues related to product quality, such as lack of taste or smell, which allows for preventative actions such as changing ingredients or production processes. As with HACCP, FMEA has certain limitations related to costs, both in terms of time and human resources. FMEA analysis is based on expert opinions, which can lead to subjectivity and a lack of a consistent approach to risk assessment. FMEA is effective in identifying potential hazards, but it does not always allow for effective risk management, as it does not take into account the actual occurrence of errors. FMEA analysis should be regularly updated to reflect changes in the production process, but this is often ignored. The method itself focuses on identifying errors and potential hazards, which can lead to a lack of attention on other important aspects of safety and product quality

Results and Discussion

The research was carried out in an SME company involved in the production of: canned and jarred vegetables, concentrates, purees, dinner additives, spices, fruit preparations and juices. For the case study, the production of canned cucumber in one-letter glass packaging was proposed (Fig.1).

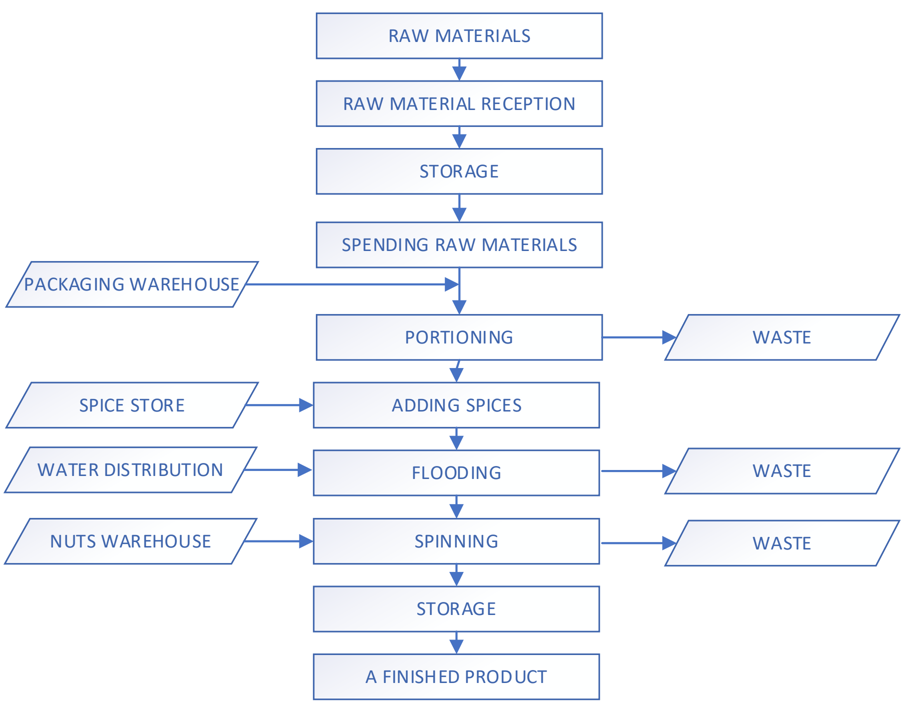

Fig.1. *Flowchart of the production process of pickled cucumbers in a 1lir jar.*

According to the principles of the HACCP system, a list of all expected biological, chemical, and physical hazards should be made at each stage specified on the diagram. These hazards should be specified as precisely as possible. In this case, the following should be taken into account: an assessment of the significance and impact of a given hazard on human health, the probability of a given hazard occurring, the possibility of survival or reproduction of microorganisms that may infect the health of the consumer, as well as the possibility of eliminating hazards. Table 1 presents a summary of hazards and identification of CCPs.

Table 1. *Hazard identification – CCPs*

Process stage	Type and source of the threat	Control	CCP
Raw material reception	Infected raw materials	approvals, visual assessment of packaging tightness	CCP 1
	Incorrect composition of raw materials	approvals, System procedure	
	Foreign bodies in raw materials	approvals, System procedure	
Storage	Development of microorganisms caused by pest activity	System procedure	CCP 2
	Growth of microorganisms caused by inappropriate temperature and humidity	System procedure	CCP 3
	Pests and their droppings	System procedure	CCP 4
Spending raw materials	Undefined threat	-	-
Portioning	Secondary human infection	GHP Code	-
	Incorrect amount/weight of cucumbers	Weighing instructions	CCP 5
Adding spices	Secondary human infection	GHP Code	-
Spinning	Secondary human infection	GHP Code	-
Storage	Development of microorganisms caused by pest activity	System procedure	-
	Growth of microorganisms caused by inappropriate temperature and humidity	System procedure	CCP 6
	Pests and their droppings	System procedure	CCP 7

The most commonly identified critical control points are the receipt of products into the warehouse and the storage of food. All potential hazards should be examined and the products accepted should be evaluated in terms of health quality. For each critical control point, so-called target values along with allowable tolerances and boundary values of specified parameters, i.e. critical values, should be established. These values should guarantee the effective elimination of the hazard. These criteria usually include indicators such as time, temperature, humidity, water activity, etc., and sometimes sensory characteristics (e.g. smell, taste, color).

The monitoring method must be strictly defined. It should specify:

- what parameters are measured,
- what are the critical limits for the measurements made,
- how, when, and with what frequency monitoring is carried out.
- whether the monitoring procedure is reliable.

Figure 2 shows the hazard identification decision tree.

For each critical control point, corrective actions must be established. These actions should allow for the immediate removal of any deviations in the values of the accepted parameters and ensure that the critical point is under control. Corrective actions should be taken after exceeding the critical value for a given point. Corrective actions should include: ways to regain control over the critical control point, methods of dealing with uncertain product (what to do with a product that was poorly stored - throw it away, test it, shorten the shelf life for consumption?).

Corrective actions should be as simple and easy to implement as possible and the personnel responsible for them should be appropriately trained. Verification aims to determine whether the procedures introduced within the HACCP system give the desired result. It should also detect any shortcomings. Activities may include, for example, reviews of records with identified deviations, determining tolerance levels, etc. Verification should be carried out by persons other than those responsible for the activities being verified. Verification should be carried out periodically in a planned manner to ensure the effective implementation of HACCP principles.

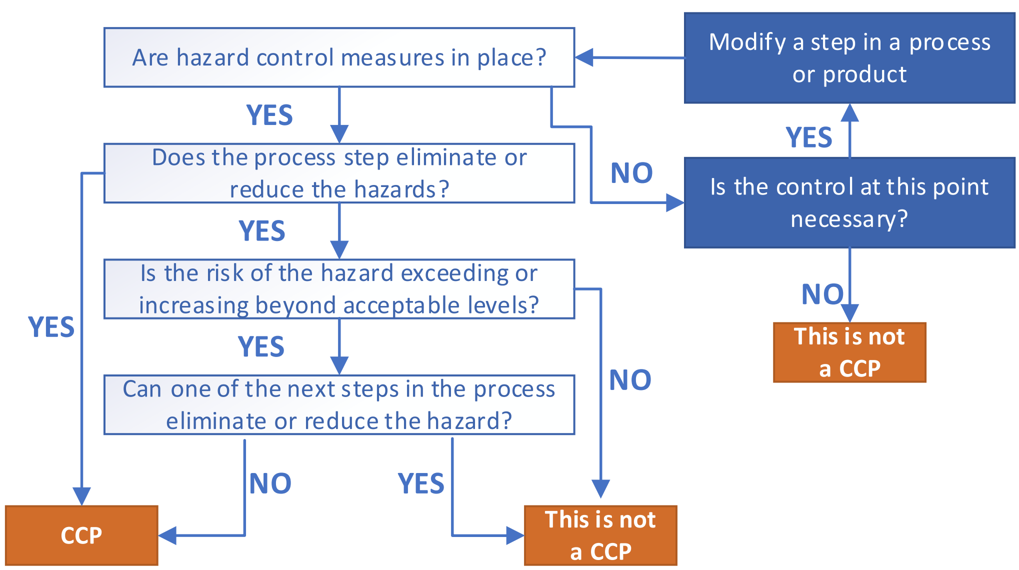

***Fig.2.** Identification of critical points of CCPs.*

The FMEA method is a widely used tool in the field of reliability engineering. It is used to identify potential failure modes in products or systems, and to analyze the effects and causes of those failures. The FMEA process begins by identifying potential failure modes based on existing information and then uses statistical methods to determine the severity, occurrence, and detectability of each failure mode (Fig.3).

The risk priority number (RPN) is calculated for each failure mode using a formula (RPN=S×O×D), and the failure modes are ranked according to their RPN value. Finally, measures are put in place to improve the reliability of the product or system by addressing the most significant failure modes. The severity (S) of a failure mode is a measure of its impact on the system, product, or customer, and is typically rated on a scale from 1 to 10. The occurrence (O) of a failure mode is a measure of its likelihood and is also rated on a scale from 1 to 10. The detectability (D) of a failure mode refers to the ease with which it can be detected and is rated on a scale from 1 to 10. Based on the results of the FEMA analysis obtained for vegetable processing products, potential product failure modes have been established. Failures with the highest number of RPNs are: Pollution of sources of vegetable (RPN=320), Lack of cold storage protection (RPN=196) and Cross-contamination (RPN=120). The potential failure factors need to be combined with the flow of vegetable products from the growing site to distribution to the customer in order to identify critical CCP control points. As shown in Table 2, the critical control points of the meat product supply chain are cultivation, distribution and transport and sales.

Table 2. *Analysis of critical control points in the supply chain of plant products*

Potential failure modes	**Link(s) of the occurrence of the failure**	**RPN**	**CCP**
Pollution of sources of vegetable	Cultivation	320	YES
Lack of cold storage protection	Distribution and transportation and sales	196	YES
Cross-contamination	Cultivation, transport, processing and sales	120	NO
False label marks	Processing and sales	56	NO
Pollution of packaging materials	Storage and distribution and transportation	36	NO

Functional requirements of vegetable processing products	Potential failure modes	Consequences of potential failures	S	Potential failure mechanism	O	Current process control	D	RPN	The link of responsibility supply chain
Preservation: The product must be able to effectively preserve the freshness and nutritional value of the vegetables for an extended period of time. *Shelf life:* The product should have a long shelf life to ensure that it can be stored for a reasonable period of time before consumption. *Food safety:* The product must be safe for consumption and should not pose a risk of food poisoning or other health hazards. *Taste and texture:* The product should retain the taste and texture of fresh vegetables as much as possible, without being overly processed or altered. *Nutritional value:* The product should retain as much of the nutritional value of the fresh vegetables as possible, and should not introduce any harmful additives or preservatives. *Convenience:* The product should be easy to use and store, and should not require extensive preparation or cooking time.	Pollution of vegetable sources	Vegetables products are polluted by bacteria such as E. coli, Salmonella, and Listeria, pesticides, heavy metals, mycotoxins, and microplastics.	8	Use of pesticides by farmers, soil contamination, water contamination, air pollution, animal waste, lack of proper sanitation and hygiene practices	5	Strictly implement the relevant access approval standards; check the "phytosanitary certificate" and the "official certificate of non-epizootic area" Testing: Regularly testing the vegetables for contaminants. Traceability: Implementing traceability systems.	8	**320**	Cultivation
	Cross-contamination	Microbes and pathogenic bacteria contaminate vegetables products	6	Cross-contamination of equipment, inadequate cleaning of equipment, the transmission of harmful microorganisms due to non-compliance with sanitary and hygienic procedures	5	Avoid workers and customers having direct contact with vegetables; implement operational prerequisite programs	4	**120**	cultivation, transport, processing and sales
	Pollution of packaging materials	Vegetables products suffer chemical pollution	4	Packing materials contain harmful components as well as mobility and diffusivity	3	Strictly implement the national technical standards and regulations of packaging materials	3	**36**	Storage, distribution and transportation
	Lack of cold storage protection	Vegetable products suffer spoilage and are polluted by spoilage organisms and pathogenic bacteria	7	The storage of fresh vegetables is incomplete, no attention is paid to securing vegetables in the warehouse	7	professional distribution teams; strengthening of temperature monitoring and records	4	**196**	Distribution and transportation, sales
	False label marks	Expired and bad vegetable products	7	Use exaggerated and false packaging to change the expired vegetables products and sell them again	4	Authenticity test; information query; monitoring and recording of expiration dates	2	**56**	Processing and sales

Fig.3. *FMEA analysis form of vegetable products*

Summary

In conclusion, this research suggests that the use of the Failure Modes and Effects Analysis (FMEA) method as support for the Hazard Analysis and Critical Control Points (HACCP) system in the food industry provides better benefits than using HACCP alone. By identifying potential failures using FMEA, the research found that the most significant risks included pollution of sources of vegetables, lack of cold storage protection, cross-contamination, and false label marks. These failures were then classified according to their Risk Priority Number (RPN) value, with the highest RPN values assigned to pollution of sources of vegetables and lack of cold storage protection. Both of these failures were defined as Critical Control Points (CCPs) and are therefore supervised and monitored. However, cross-contamination and false label marks were not defined as CCPs and may require additional attention. Overall, this research suggests that the combination of HACCP and FMEA can be an effective way to identify and mitigate risks in the food industry because:

- Together, these methods provide a comprehensive approach to identifying and assessing risks in the food industry.
- The combination of HACCP and FMEA allows for a more detailed and thorough assessment of risks, leading to more effective risk management. By identifying potential hazards and analyzing their potential effects, companies can take proactive measures to prevent or mitigate these risks.
- Using FMEA as support for HACCP can lead to more efficient risk management. By identifying potential hazards early on in the process, companies can take steps to prevent them from occurring, rather than having to react to problems after they have already occurred.
- By using both HACCP and FMEA, companies can continuously monitor and improve their food safety processes. This helps ensure that risks are identified and addressed in a timely manner, leading to safer products for consumers.

Safety in the food processing industry is associated with both the safety of workers and the sanitary safety of the produced food, and proper management procedures are crucial here [15, 16]. Regardless of that, technological measures related to proper preparation of surfaces [17], protective coatings [18, 19], special coatings [20, 21], and applied joints [22] will be helpful. The appropriate design of buildings [23] and the organization of internal and external traffic [24] also have a significant impact. Useful tools will be proper mathematical procedures [25, 26] that enable effective reduction of a very large number of process factors, often mutually correlated, to a much smaller but easier-to-analyze set [27]. Then, known statistical analysis procedures of DOE methodology [28-30] can be applied, including non-parametric approaches [31-33] and those specific to small sample sizes [34-36].

References

[1] A. Pacana, R., Ulewicz. Analysis of causes and effects of implementation of the quality management system compliant with ISO 9001. Pol. J. Manag. Stud. 21 (2020) 283-296. https://doi.org/10.17512/pjms.2020.21.1.21

[2] J.C Lee et al. Implementation of Food Safety Management Systems along with Other Management Tools (HAZOP, FMEA, Ishikawa, Pareto). The Case Study of Listeria monocytogenes and Correlation with Microbiological Criteria. Foods 10 (2021) art.2169. https://doi.org/10.3390/foods10092169

[3] D. Siwiec et al. Concept of a model to predict the qualitative-cost level considering customers' expectations. Pol. J. Manag. Stud. 26 (2022) 330-340. https://doi.org/10.17512/pjms.2022.26.2.20

[4] J. Rosak-Szyrocka, A.A. Abbase. Quality management and safety of food in HACCP system aspect. Prod. Eng. Arch., 26 (2020) 50-53. https://doi.org/10.30657/pea.2020.26.11

[5] Y.-M., Sun, H.W. Ockerman. A review of the needs and current applications of hazard analysis and critical control point (HACCP) system in foodservice areas. Food Control 16 (2005) 325-332. https://doi.org/10.1016/j.foodcont.2004.03.012

[6] K.V. Kotsanopoulos, I.S. Arvanitoyannis. The Role of Auditing, Food Safety, and Food Quality Standards in the Food Industry: A Review. Compr. Rev. Food Sci. Food Saf. 16 (2017) 760-775. https://doi.org/10.1111/1541-4337.12293

[7] P.J. Panisello, P.C. Quantick. Technical barriers to Hazard Analysis Critical Control Point (HACCP). Food Control 12 (2001) 165-173. https://doi.org/10.1016/S0956-7135(00)00035-9

[8] V. Dadi et al. Agri-Food 4.0 and Innovations: Revamping the Supply Chain Operations. Prod. Eng. Arch. 27 (2021) 75-89. https://doi.org/10.30657/pea.2021.27.10

[9] M. Ingaldi, S.T. Dziuba. Market of the organic products in Poland according to potential customers, In: 16th Int. Multidiscip. Sci. GeoConf. Surv. Geol. Mining Ecol. Manag. SGEM 3 (2016), 341-348. https://doi.org/10.5593/SGEM2016/B53/S21.044

[10] S.T. Dziuba, M. Ingaldi, Systems providing food safety and its perception by polish customers – introduction, In: 17th Int. Multidiscip. Sci. GeoConf. Surv. Geol. Mining Ecol. Manag. SGEM 17 (2017) 854-860. https://doi.org/10.5593/sgem2017/53/S21.104

[11] N. Baryshnikova et al. Management approach on food export expansion in the conditions of limited internal demand. Pol. J. Manag. Stud. 21 (2020) 101-114. https://doi.org/10.17512/pjms.2020.21.2.08

[12] R Wolniak. Problems of use of FMEA method in industrial enterprise. Prod. Eng. Arch. 23 (2019) 12-17. https://doi.org/10.30657/pea.2019.23.02

[13] R. Ulewicz. Practical Application of Quality Tools in the Cast Iron Foundry. Manuf. Technol. 14 (2014) 104-111. https://doi.org/10.21062/ujep/x.2014/a/1213-2489/MT/14/1/104

[14] R. Ulewicz et al. Implementation of logic flow in planning and production control, Manag. Prod. Eng. Rev. 7 (2016) 89-94. https://doi.org/10.1515/mper-2016-0010

[15] R. Ulewicz et al. Implementation of logic flow in planning and production control, Manag. Prod. Eng. Rev. 7 (2016) 89-94. https://doi.org/10.1515/mper-2016-0010

[16] N. Baryshnikova et al. Management approach on food export expansion in the conditions of limited internal demand, Pol. J. Manag. Stud. 21 (2020) 101-114. https://doi.org/10.17512/pjms.2020.21.2.08

[17] N. Radek et al. The influence of plasma cutting parameters on the geometric structure of cut surfaces, Mater. Res. Proc. 17 (2020) 132-137. https://doi.org/10.21741/9781644901038-20

[18] N. Radek et al. Technology and application of anti-graffiti coating systems for rolling stock, METAL 2019 – 28th Int. Conf. Metall. Mater. (2019) 1127-1132. ISBN 978-8087294925

[19] N. Radek et al. Formation of coatings with technologies using concentrated energy stream, Prod. Eng. Arch. 28 (2022) 117-122. https://doi.org/10.30657/pea.2022.28.13

[20] N. Radek et al. Microstructure and tribological properties of DLC coatings, Mater. Res. Proc. 17 (2020) 171-176. https://doi.org/10.21741/9781644901038-26

[21] N. Radek et al. Influence of laser texturing on tribological properties of DLC coatings, Prod. Eng. Arch. 27 (2021) 119-123. https://doi.org/10.30657/pea.2021.27.15

[22] N. Radek et al. The impact of laser welding parameters on the mechanical properties of the weld, AIP Conf. Proc. 2017 (2018) art.20025. https://doi.org/10.1063/1.5056288

[23] J.M. Djoković et al. Selection of the Optimal Window Type and Orientation for the Two Cities in Serbia and One in Slovakia, Energies 15 (2022) art.323. https://doi.org/10.3390/en15010323

[24] A. Bąkowski et al. Frequency analysis of urban traffic noise, ICCC 2019 20th Int. Carpathian Contr. Conf. (2019) 1660-1670. https://doi.org/10.1109/CarpathianCC.2019.8766012

[25] B. Jasiewicz et al. Inter-observer and intra-observer reliability in the radiographic measurements of paediatric forefoot alignment, Foot Ankle Surg. 27 (2021) 371-376. https://doi.org/10.1016/j.fas.2020.04.015

[26] L. Cedro. Model parameter on-line identification with nonlinear parametrization – manipulator model, Technical Transactions 119 (2022) art. e2022007. https://doi.org/10.37705/TechTrans/e2022007

[27] J. Pietraszek, E. Skrzypczak-Pietraszek. The uncertainty and robustness of the principal component analysis as a tool for the dimensionality reduction. Solid State Phenom. 235 (2015) 1-8. https://doi.org/10.4028/www.scientific.net/SSP.235.1

[28] J. Pietraszek et al. The parametric RSM model with higher order terms for the meat tumbler machine process, Solid State Phenom. 235 (2015) 37-44. https://doi.org/10.4028/www.scientific.net/SSP.235.37

[29] J. Pietraszek, A. Szczotok, N. Radek. The fixed-effects analysis of the relation between SDAS and carbides for the airfoil blade traces. Archives of Metallurgy and Materials 62 (2017) 235-239. https://doi.org/10.1515/amm-2017-0035

[30] R. Dwornicka, J. Pietraszek. The outline of the expert system for the design of experiment, Prod. Eng. Arch. 20 (2018) 43-48. https://doi.org/10.30657/pea.2018.20.09

[31] J. Pietraszek. Fuzzy regression compared to classical experimental design in the case of flywheel assembly, LNAI 7267 LNAI (2012) 310-317. https://doi.org/10.1007/978-3-642-29347-4_36

[32] J. Pietraszek. The modified sequential-binary approach for fuzzy operations on correlated assessments, LNAI 7894 (2013) 353-364. https://doi.org/10.1007/978-3-642-38658-9_32

[33] J. Pietraszek et al. The fuzzy approach to assessment of ANOVA results, LNAI 9875 (2016) 260-268. https://doi.org/10.1007/978-3-319-45243-2_24

[34] A. Gądek-Moszczak et al. The bootstrap approach to the comparison of two methods applied to the evaluation of the growth index in the analysis of the digital X-ray image of a bone regenerate, Studies in Computational Intelligence 572 (2015) 127-136. https://doi.org/10.1007/978-3-319-10774-5_12

[35] J. Pietraszek, L. Wojnar. The bootstrap approach to the statistical significance of parameters in RSM model, ECCOMAS Congress 2016 Proc. 7th Europ. Cong. Comput. Methods in Appl. Sci. Eng. 1 (2016) 2003-2009. https://doi.org/10.7712/100016.1937.9138

[36] J. Pietraszek et al. Challenges for the DOE methodology related to the introduction of Industry 4.0. Prod. Eng. Arch. 26 (2020) 190-194. https://doi.org/10.30657/pea.2020.26.33