SYSTEM SAFETY: HUMAN - TECHNICAL FACILITY – ENVIRONMENT
6(1), 2024, pp. 330-338

RISK ASSESSMENT AND ANALYSIS IN TOY PRODUCTION: A CASE STUDY OF PLASTIC BLOCK MANUFACTURING USING PARETO-LORENZ AND FMEA METHODS

DOI: 10.2478/czoto-2024-0035
Received: 01/12/2024
Accepted: 18/12/2024

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Abstract: This paper presents a comprehensive risk assessment and analysis in the production of plastic toys - specifically building blocks - conducted using the Pareto-Lorenz diagram and the Failure Mode and Effects Analysis (FMEA) method. The study addresses the challenges faced by toy manufacturers, particularly in the small and medium-sized enterprise (SME) sector, in meeting stringent safety and quality requirements for children's toys. The Pareto-Lorenz diagram identified the most frequent nonconformities in the production process, revealing that small protruding parts and sharp edges accounted for 71.65% of all detected defects. The FMEA method, applied in a novel approach, allowed for the prioritization of risks and the identification of key areas for improvement, such as material selection, injection molding parameters, and quality control processes. Based on the findings, the study proposes targeted optimization measures to enhance product quality, safety, and production efficiency. These results contribute to the body of knowledge on risk management in toy manufacturing and offer practical solutions for improving compliance with industry standards.
Keywords: risk assessment, toys production, Pareto-Lorenz diagram, FMEA method, quality optimization

1. INTRODUCTION

Toy production involves numerous challenges, both at the design and production stages. In the face of growing and changing customer requirements and legal regulations, toy manufacturers must not only ensure the quality of their products but also effectively manage the risks associated with production. Risk assessment and analysis in this context are key elements in ensuring product safety, protecting customers, and minimizing potential economic or reputational losses for manufacturers.

Toys, defined as products designed or intended for play by children under 14 years of age, must meet stringent safety requirements in Europe, considered among the most restrictive globally (Rozporządzenie Ministra Rozwoju i Finansów z dn. 20.10.2016 w sprawie wymagań dla zabawek). EU regulations derived from Directive 2009/48/EC on toy safety define essential requirements to ensure that toys placed on the market do not

pose risks to users. These regulations emphasize the responsibility of manufacturers, importers, distributors, and national authorities in ensuring compliance.
The importance of risk assessment is underscored by the growing demand for sustainable and efficient production processes. Pacana et al. (2024) introduced a Quality Life Cycle Assessment (QLCA) model that integrates qualitative and environmental aspects into product development, highlighting the role of sustainability in modern manufacturing. Similarly, Rosyidi et al. (2024) presented an integrated optimization model to address procurement and production lot-sizing challenges, showcasing the value of systematic approaches in reducing risks and improving process efficiency.
This paper aims to evaluate the effectiveness of the Pareto-Lorenz diagram and the FMEA method, applied in a novel manner, for analyzing and assessing risk in the production of plastic toys, specifically building blocks. By identifying the most common threats and nonconformities in the production process, the study proposes measures to minimize or eliminate risks. The Pareto-Lorenz diagram, based on the "20-80" rule, is employed to prioritize nonconformities (Pacana and Czerwińska, 2019; Ulewicz, 2014). Meanwhile, the FMEA method, as adapted from the AIAG and VDA Handbook (2019), is used to identify potential nonconformities, their causes, and effects, assigning priorities for action (Jagusiak-Kocik, 2023; Sharma and Srivastava, 2018). The effectiveness of plastic production machinery in improving manufacturing processes has also been examined in the literature (Mielczarek and Krynke, 2018).

2. OBLIGATIONS OF THE TOY MANUFACTURER

Every manufacturer producing toys is obliged to (Bezpieczeństwo Zabawek w UE. Praktyczny przewodnik przedstawiający obowiązki prawne producentów, importerów i dystrybutorów, Rozporządzenie Ministra Rozwoju i Finansów z dn. 20.10.2016 w sprawie wymagań dla zabawek):
- design and manufacture the toy in accordance with the essential safety requirements. Each toy must not pose a threat to the health or safety of children and other users. It is necessary to comply with the regulations related to the properties of toys (chemical, physical and mechanical) as well as to the regulations related to hygiene, flammability and radioactivity,
- prepare technical documentation containing all information on the compliance of the toys with all the safety requirements specified in the directive (including a detailed description of the design and production, including a list of components, materials used, chemical safety data sheets from suppliers, results of safety assessments, addresses of production sites, test reports). Such documentation should be kept for a period of at least 10 years from the moment the toy is placed on the market and written in an official language of an EU Member State,
- conduct a safety assessment (before the toy is put on sale). This involves identifying the potential hazards that a given toy may pose (chemical, physical, mechanical, electrical, flammability, hygiene, radioactivity hazards) and analysing the potential exposure to such hazards,
- before the toy is put on sale, to draw up an EC declaration of conformity (DoC), which is kept for at least 10 years. In this document, the manufacturer certifies that the toy meets all safety requirements and assumes responsibility for the toy's compliance with the regulations. This declaration clearly states which toy it refers to and must be translated into all the languages of the Member States where the toy is sold,

- place the CE conformity marking and identification number on the toy. CE means that the manufacturer indicates that the toy meets all the relevant requirements specified in EU legislation. Such marking is placed on the toy, label or packaging in a visible, permanent and legible manner (it is also recommended that in the case of online sales such marking be placed on the website). If the toy is small, the CE marking may be placed on the label or attached leaflet. Toys should also have a type name, batch number, series or model or other information enabling their identification. If the size or nature of the toy does not allow this, the required information may be placed on the packaging or in a document attached to the toy,
- ensure that procedures are applied to ensure the conformity of series production (even when the design or characteristics of the toy are changed),
- mark the toy or, if this is not possible, its name and address on its packaging or in a document accompanying the toy,
- ensure that safety information and instructions for use are in the appropriate language,
- display in a visible, legible and comprehensible manner and in a language or languages determined by each Member State, where necessary, warnings (on the toy, an accompanying label or on the packaging and in the instructions),
- bring non-conforming toys into conformity, recall them or withdraw them from the market,
- provide the national authorities with the documentation necessary to establish the conformity of the toy, in response to a reasoned request,
- in the case of toys that may present a risk, carry out a sample test of the toy,
- keep a register of complaints relating to non-conforming toys concerning toy recalls.

3. METHODOLOGY

A small company based in the Silesian Voivodeship was selected for the risk assessment and analysis. This company manufactures plastic products such as decorative elements for home and garden, garden toys and blocks. These blocks are manufactured in various sizes, but the majority of production is based on large blocks intended for children aged around 2-4. These are typical construction blocks manufactured in many simple shapes and colours, and certified plastic is used for production.

The risk analysis (Nedeliaková et al. 2021) was conducted in second quarter 2024, and the scope of the research covered the stages of production of the blocks, from design, through production, to final quality control. Risk identification included research consisting of, among others, interviews with company employees to identify potential sources of risk, analysis of production processes with an emphasis on potential weak points in these processes and documentation research. Based on documentation and their own experience, production workers were tasked with identifying the most common nonconformities in the production of blocks.

The risk assessment was performed using two tools: the Pareto-Lorenz diagram and FMEA analysis (Czerwińska and Piwowarczyk, 2022, Furman and Małysa, 2023, Jagusiak-Kocik, 2023, Knop and Ulewicz, 2022, Pacana and Czerwińska, 2020, Siwiec and Pacana, 2021).

The Pareto-Lorenz diagram (Pacana and Czerwińska, 2019, Ulewicz, 2014) allows us to determine which nonconformities occur most frequently in the examined research period, or are the cause of the greatest losses and which should be eliminated first. The Pareto-Lorenz diagram is based on the "20-80" rule, which means that usually a small number of

causes (from 20 to 30%) are responsible for a large part (from 70 to 80%) of the effect that occurred.
FMEA (AIAG and VDA FMEA Handbook, 2019, Jagusiak-Kocik, 2023, Plinta et al., 2021, Sharma and Srivastava, 2018, Shuyuan et al., 2014, Wolniak, 2019), on the other hand, allows us to identify potential nonconformities in the production process and their causes and effects, as well as select the Action Priority, which prioritizes actions.
The Pareto-Lorenz diagram was used to prioritize nonconformities occurring during the production of plastic toys - blocks, while the FMEA method in a new approach was used to analyze the risk of the manufacturing process of these toys.

4. RESULTS

In the examined period of the second quarter 2024, the 10 most frequent nonconformities of toys – plastic blocks – were selected for analysis. This number of nonconformities was indicated by production workers. For the purposes of the work, they were marked from N1 to N10 and these are nonconformities such as:
N1 - blocks with incorrect dimensions,
N2 - deformed shapes of blocks,
N3 - unevenly colored blocks,
N4 - irregularities on the blocks after the injection process,
N5 - air bubbles on the blocks after the injection process,
N6 - cracks on the surface of the blocks after the injection process,
N7 - small protruding parts on the blocks,
N8 - sharp edges on the surfaces of the blocks,
N9 - spots on the surface of the blocks,
N10 - contamination on the surface of the blocks.
These nonconformities were arranged from the most frequent to the least frequent (how many times a given non-conformity was detected during quality control). Nonconformities together with the adopted symbols and the frequency of their occurrence in quality control (after sorting) are presented in Table 1.

Table 1
The structure of nonconformities of toys – plastic blocks in the studied period

Nonconformity designation	Nonconformity name	Ranking of nonconformities (pcs.)
N7	small protruding parts on the blocks	98
N8	sharp edges on the surfaces of the blocks	84
N4	irregularities on the blocks after the injection process	21
N3	unevenly colored blocks	16
N10	contamination on the surface of the blocks	11
N5	air bubbles on the blocks after the injection process	8
N9	spots on the surface of the blocks	7
N2	deformed shapes of blocks	5
N1	blocks with incorrect dimensions	3
N6	cracks on the surface of the blocks after the injection process	1

The percentage share and the cumulative percentage of the number of nonconformities are presented in Table 2.

Table 2
Percentage and cumulative share of nonconformities in the research period

Nonconformity designation	Nonconformity name	Percentage share	Cumulative share
N7	small protruding parts on the blocks	38,58	38,58
N8	sharp edges on the surfaces of the blocks	33,07	71,65
N4	irregularities on the blocks after the injection process	8,27	79,92
N3	unevenly colored blocks	6,30	86,22
N10	contamination on the surface of the blocks	4,33	90,55
N5	air bubbles on the blocks after the injection process	3,15	93,70
N9	spots on the surface of the blocks	2,76	96,46
N2	deformed shapes of blocks	1,97	98,43
N1	blocks with incorrect dimensions	1,18	99,61
N6	cracks on the surface of the blocks after the injection process	0,39	100,00

Based on the data presented in Table 2, a Pareto-Lorenz diagram was created, as shown in Figure 1.

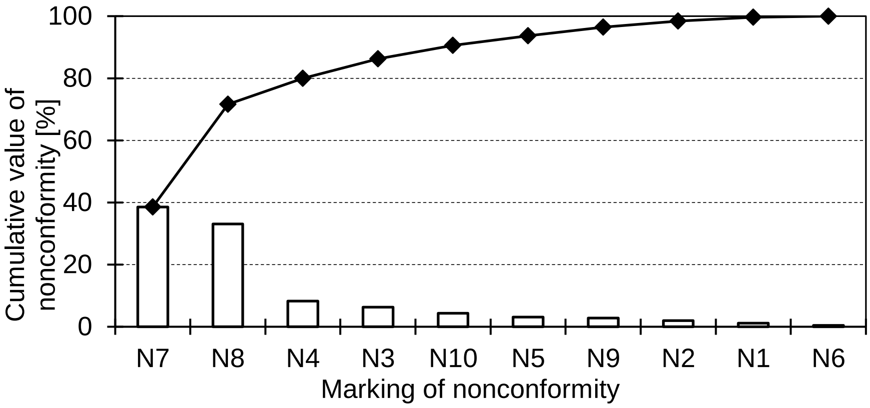

Fig. 1. Pareto-Lorenz diagram for the nonconformities of toys - plastic blocks

The diagram presented in Figure 2 shows that 20% of causes cause 71.65% of effects. In addition, it can be stated that 71.65% of all nonconformities of toys - plastic blocks detected by quality control are caused by 2 non-conformities: protruding small parts on blocks and sharp edges on blocks surfaces. The remaining 8 nonconformities are responsible for 28.35% of effects. The company should focus on, among other things, controlling the production process of the blocks, including optimizing the molding process, automatic removal of excess material, and quality control, including visual inspection.
The next step was risk analysis using one of the quality management methods – FMEA method in the new approach. The approach to FMEA method according to the new AIAG&VDA approach assumes conducting the analysis in 3 steps: step 1, i.e. system analysis consisting of defining the scope of analysis, structure analysis and function analysis, step 2 is error analysis and risk assessment with optimization and step 3 is risk communication by documenting the results. For the needs of the work, an FMEA sheet

was created consisting of 2 parts - the first one is structure and function analysis, and the second one is nonconformity analysis and risk analysis. This sheet was slightly modified for the needs of the work and does not contain certain information about the company, e.g. responsible persons, dates or numbers that define individual parts of the product). The sheets do not include a step regarding optimization and risk communication.

In the new version of the FMEA method, an additional step is to define the scope, using the 5T method (Target, Time, Team, Tool, Task). In this work, the main goal (Target) was to analyze and assess the risk in the manufacturing process of plastic blocks, in the period of 1 quarter (Time), with the participation of production workers, the production manager, the quality director and the general director (Team), using the FMEA method with 7 steps (Tool), with tasks assigned to each team member (Task). In the sheet presented in Table 3 in the structure analysis, the general phases of the manufacturing process are presented, in the work elements - the general names of machines, materials and devices.

Table 3
FMEA method for the analysis of the toy process - plastic blocks - new version (step 2 and 3)

Structure analysis (step 2)			**Function analysis (step 3)**		
Name of the process	**Process step**	**Process work element**	**Function of the Process Item**	**Function of the Process Step and Product Characteristic**	**Function of the Process Work Element and Process Characteristic**
Manufacturing process of toys – plastic blocks	designing blocks, making a prototype	computer programs such as CAD, 3D printer, designer	ensuring that the bricks meet the needs of customers and that they will match each other	blocks with appropriate shapes and dimensions	appropriate version of the CAD program, 3D printer with the right parameters
	material selection	plastic, plastic mixers, dyes, human	ensuring that the blocks are made of certified, safe plastic and dyes	selected suitable material and dyes	type of material (e.g. strength, impact resistance), appropriate dyes
	injection	mold, injection molding machines, man	ensuring that the mold into which the plastic is injected is precisely designed	blocks of the desired shape and dimensions	injection temperature, injection time
	cooling and disassembly	form pipe system filled with water or coolant, removal robots, human	ensuring that the blocks will have the right hardness	cooled blocks ready for further processing	cooling parameters
	removal of excess plastic	cutting machines, other sprue removal machines, human	ensuring that the blocks do not have excess material	blocks without redundant elements	cutting machine parameters
	grinding and smoothing	grinders, polishers, man	ensuring that the blocks do not have sharp edges	blocks ready for the next stages	parameters of the grinder/ polisher

	quality control	measuring systems, microscopes, machines for testing resistance to impact,man	ensuring that the finished blocks will meet the requirements	blocks that meet the requirements	parameters of measuring devices
	safety testing	measuring systems, microscopes	ensuring that the blocks are safe to use	ready-to-pack blocks	parameters of measuring devices

Step 4 contains the first assessment – severity, and step 5, in addition to the assessments of occurrence and detection, contains a description of preventive actions and the Action Priority indicator (table 4).

Table 4
FMEA method for the analysis of the toy process - plastic blocks - new version (step 4 and 5)

Failure analysis (step 4)				**Risk analysis (step 5)**			
Failure Effect	**Severity (S)**	**Failure mode of the focus element**	**Failure Cause of the work element**	**Current Prevention Control**	**Occurrence (O)**	**Detection (D)**	**AP**
the blocks may not fit together	6	measurement errors in the design of blocks	inadequate CAD software, lack of procedures	training designers in the use of CAD software and measuring tools	2	2	L
blocks may be too weak or have the wrong texture	5	use of the wrong material	incorrect selection of plastic	use of certified materials in accordance with safety standards	2	1	L
inaccurate dimensions of the blocks, distortion	6	improper formation of blocks	injection temperatures too high or too low, wrong pressure, inaccurate injection machine settings	regular inspections and maintenance of injection molding machines	3	3	L
blocks can warp, deform, or crack	6	improper cooling	short cooling time, uneven cooling of the mold	modernization of cooling systems (e.g. precisely designed cooling ducts	3	2	L
blocks can have sharp edges	5	surface irregularities	failure to remove excess material	regular inspection of injection moulds	2	1	L
blocks may have an uneven surface	5	failure to move risers	imprecise cutting of risers or grinding errors	implementation of automatic visual inspection systems	2	1	L

blocks have functional defects, which can lead to complaints or even product recalls	6	insufficient quality control	unsatisfactory quality control procedure, lack of proper testing, imprecise measurements	increase the number of control tests at every stage of production	4	4	L
release of blocks that do not meet safety standards	8	no safety testing	insufficient resources (lack of testing equipment	investments in safety testing equipment and training	3	2	M

The new approach of the FMEA method confirmed the low importance of these types of failures, because using the AP matrix they were read as errors of low Priority indicator. However, in the case of errors such as: “no safety testing” the AP indicator is already marked as Medium Priority, which means that the FMEA analysis team should take preventive and detection activities.

4. CONCLUSION

The paper presents a comprehensive analysis and risk assessment in the production process of toys – plastic blocks, carried out on the basis of the Pareto-Lorenz diagram and the FMEA method. The research revealed that the biggest quality problems, responsible for the majority of nonconformities (71.65%), result from the presence of small, protruding parts (N7) and sharp edges (N8) on the blocks. These two key problems are directly related to machining and forming processes, indicating the need for optimization. The FMEA method made it possible to accurately identify potential process defects, their causes and effects. Key risks include improper material selection, nonconformities in injection processes, and errors in quality control systems. The analysis also showed the need to improve defect detection and process parameters to prevent non-conformities at an early stage of production.

Based on the research results, optimization actions can be proposed, m.in.: implementation of more precise machining technologies, such as automatic grinding, to eliminate sharp edges, upgrading injection molds and improving injection parameters to reduce protruding components, optimizing cooling and injection parameters such as temperature, pressure, and cycle time, which will reduce the risk of deformation and other defects, using more resistant materials that will reduce cracks and other defects, introducing advanced measurement systems that automatically detect surface and edge defects, expanding safety testing, regular training of employees on the identification and elimination of defect causes and systematic audits of production processes and updating control procedures. The proposed actions will significantly improve the quality of manufactured toys and the safety of users, which will improve the competitiveness of the company on the market. Process optimization will minimize the risk of non-conformance, increase production efficiency, and reduce costs associated with complaints and material losses.

The work does not include the step of the FMEA method regarding the optimization of activities, which may be the next step in further research. A certain limitation in further research may be the fact that the company presented in the paper is a small company, employing a small number of people.

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