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OPERATIONAL RELIABILITY MODEL OF THE PRODUCTION LINE

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Summary. The proposed model has been created for the purpose of risk analysis in the production of a medical device. The requirement for risk management and risk analysis is articulated both in ISO 13485 and MDD Directive 93/42. The presented method of risk modeling is exemplified by risk analysis in the production of a medical device, namely a dental composite.

Key words: probabilistic networks, knowledge engineering, reliability.

INTRODUCTION

The concept of operational reliability model is related to the treatment of computer models as a way of knowledge representation. In this approach a model is treated as an engineering product, whose basic form of application is to build it in the information infrastructure of production processes management system. Such a reliability model requires certain functional properties and operational scenarios.

To meet these requirements it needs to broaden the conceptual system of classical reliability engineering with conceptual models used in knowledge engineering and artificial intelligence. In the context of the reliability concept, we refer not only to the machinery and equipment but the entire production process (process reliability), and reliability is treated as an aspect of predictability and repeatability of processes.

Application of knowledge engineering to reliability modeling has the effect that the model is created on the way through the transition from the representation of knowledge expressed in natural language to the form expressed in a formal and executable language. In this process of knowledge translation, machine learning algorithms based on previously gathered empirical facts play an important role. The model functions as a knowledge base (or part thereof) answering the questions asked by the user or another system. It is important that these responses are generated through automated inference mechanisms and not just a simple search. Achieving this functionality requires the use of special knowledge representation languages.

In the case of reliability models functioning as knowledge representation system their ability is required of conceptual integration with classical reliability theory. This requirement is fulfilled to a large extent by the language of Bayesian networks. Hence their use in the reliability modeling of a production line.

OBJECT AND METHOD OF RELIABILITY MODELING

Application of Bayesian networks to reliability modeling is shown on the example of a medical device production line. Products in that category are subject to special requirements arising inter alia from the European Directive MDD93/42 and the ISO 13485 standard. In the process of medical devices manufacturing must be consciously and rationally justified by the methods used for risk management. Reliability model of the production process is treated as one of the main elements of risk management system.

The production process in this case is cyclical and the production cycle is a sequence of specific actions (operations) leading to the final product that meets the relevant standards and requirements of the user. The structure of that process is shown in Figure 1.

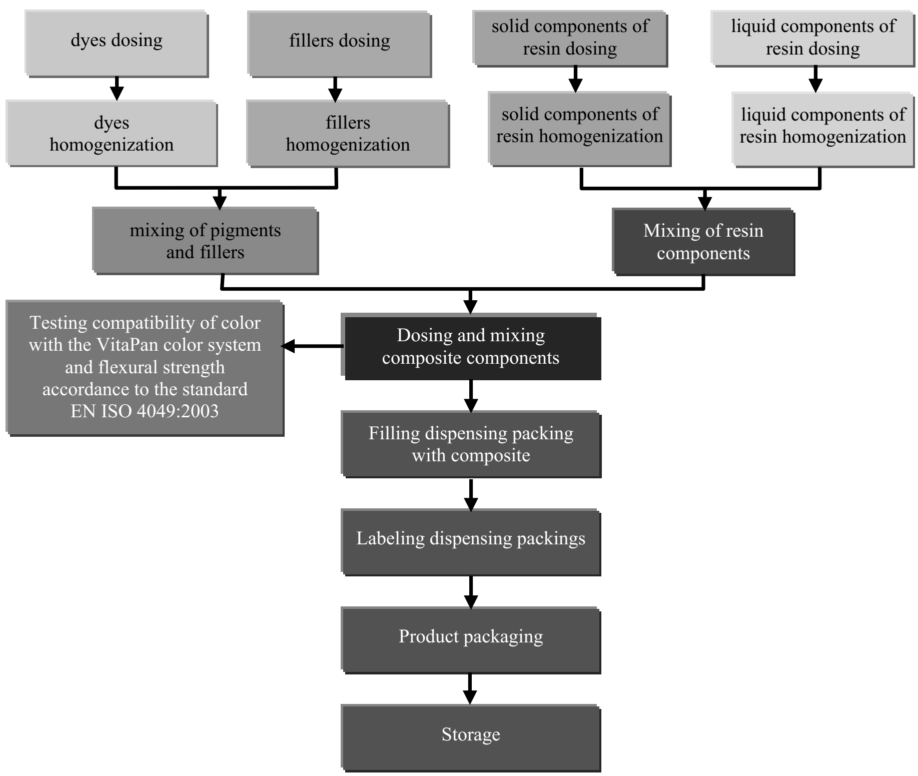

Fig. 1. Structure of dental composite manufacturing process

The conceptualization of reliability process in this case consists of product requirements specification of each operation by projecting back the final product requirements and then identification of the events conditioning the fulfillment of requirements specific for each operation.

In the classical reliability engineering, reliability model of the considered process would most likely be created in the technique of event trees or fault trees. An example of such a model is shown in Figure 2. Each operation involves nodes representing the occurrence of adverse events or non-occurrence required events and deterministic fusion node representing the cumulative effect of these events (Fig. 3).

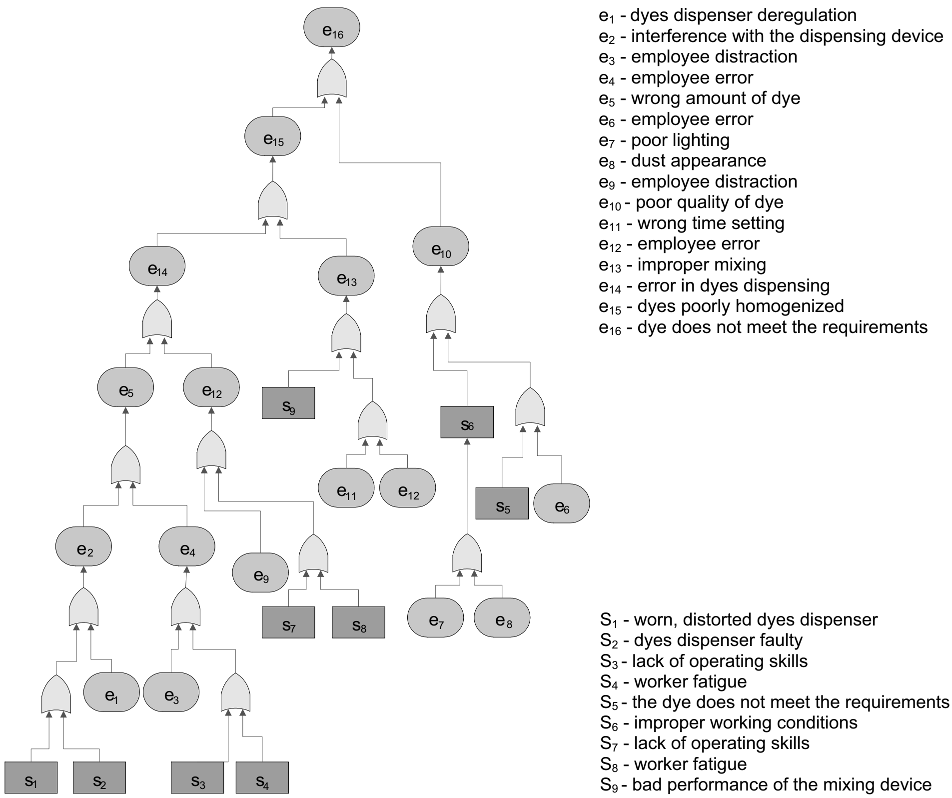

Fig. 2. Elementary Bayesian network

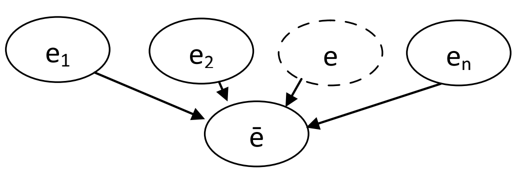

Fig. 3. Elementary Bayesian network

If any of the events alone is sufficient for the failure of the operation, then the resulting node "e" can be modeled as an operation "Noisy-Or", being a probabilistic counterpart of the logical "OR". The additional expressiveness can be achieved by applying the operations "Noisy-Or" of "leakage" (leakage), which is interpreted as the probability that the result of the technological operations will be negative, although not all the required events which occurred were negative. In other words, a “leak” is interpreted as a kind of epistemic uncertainty (resulting from incomplete knowledge).

RELIABILITY MODEL OF PRODUCTION PROCESS

Bayesian network as a reliability model of dental composite production process is shown in Fig.4. Groups of operations from Fig.1 are distinguished with different colors.

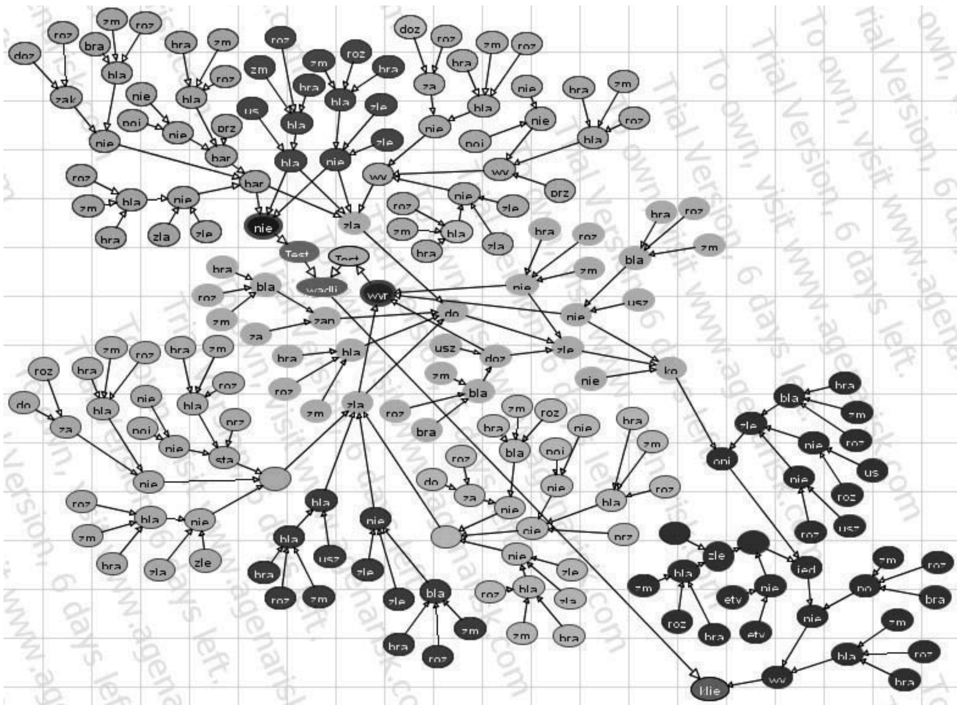

Fig. 4. Bayesian network as a reliability model of dental composite production process

Probability distributions of events represented by the network nodes were determined partly on the basis of expert estimates and based on the data collected in the enterprise management system.

As already mentioned, the operational use of the model depends on asking questions and getting answers generated by inference algorithms.

There are two basic types of inference. Predictive inference from causes to effects (“what if”) and explanatory inference - from the effects to causes (diagnostic reasoning). The questions are formulated in such a way that the values of nodes that correspond to known facts (may be with accuracy to probability distribution) are fixed and then there are calculated probability distributions corresponding to nodes representing that what we ask for, so the answers are obtained with an accuracy of probability distribution. What is known can be regarded as certain (hard evidence) or burdened with varying degrees of uncertainty (soft evidence) and such uncertain evidence is represented with accuracy to the probability distribution. Usually the probability is asked of successful completion of each operation, and the likelihood of successful completion of the process by obtaining a final product complying with the requirements.

CONCLUSIONS

The paper presents the problem of process reliability modeling using Bayesian networks technology. Models made in this technology meet the requirements of being a knowledge representation system, that is, have the characteristic of adaptability, i.e. automatic tuning the model to the specific environment of its use by machine learning on empirical examples. Such models can be used to asking questions concerned with risk management in production processes and getting answers by inference mechanisms prediction and explanation.

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MODEL OPERACYJNO-NIEZAWODNOŚCIOWY LINII PRODUKCYJNEJ

Streszczenie. Zaproponowany model utworzony został dla potrzeb analizy ryzyka przy produkcji wyrobu medycznego. Wymóg zarządzania ryzykiem i przeprowadzania analizy ryzyka występuje zarówno w normie ISO 13485 jak i dyrektywie MDD 93/42. Przedstawiona została metoda modelowania ryzyka dla potrzeb przeprowadzania analizy ryzyka przy produkcji wyrobu medycznego, jakim jest kompozyt stomatologiczny.

Słowa kluczowe: sieci probabilistyczne, inżynieria wiedzy, niezawodność.

APPLICATION OF THE OPERATIONAL RELIABILITY MODEL TO THE RISK ANALYSIS IN MEDICAL DEVICE PRODUCTION

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Summary. We present an application of the Bayesian network model to the risk analysis of the operational reliability of the dental composite material production line. The model is a computational tool meeting the risk management requirements formulated in the directive MDD 93/42 and the standard ISO 13485 concerning medical devices.

Keywords: probability networks, risk analysis, reliability

INTRODUCTION

This paper is devoted to the application of mathematical approach of Bayesian networks to model process reliability of production lines. The starting point of this work is the computational model, which we have recently developed [Bartnik, Marciniak 2011]. The model has the properties of the adaptive data base using the algorithms of machine learning applied to the sets of systematically stored empirical data to calibrate model parameters. This approach allows for addressing specific questions using automatic inference mechanisms. The operational reliability (process reliability) is defined as the probability that the product obtained in the production satisfies appropriate standards, customer and legislatory demands. Fulfilling all these demands depends on many random factors, which may significantly influence the quality of the final product.

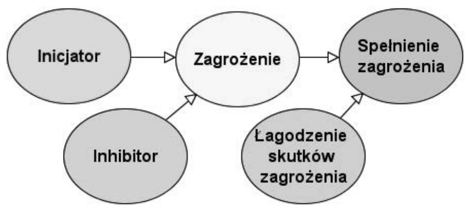
MODEL AND METHODS

The object of our study is a technological line for production of dental composite materials.

Production process is referred to as a sequence of the operations leading to the final product. During each operation there are external factors, related to the operator or machines used, which may endanger the results by causing the so called hazard initiating event. However, an occurrence of the initiating event does not necessarily lead to the production of an invalid final product, especially if hazard inhibiting events are possible (hazard inhibitors).

Hazard situations may lead to the danger scenario with a given probability. The results of the hazard depend on the possibility of the events mitigating the negative effects. One established method to model such systems is to use Bayesian networks. The model we apply is based on 5 nodes connected by the cause-effect relations (for details see Fig. 1).

For each operation of the technological process after the identification of a hazard, one or several such diagrams can be created, depending on the number of different types of hazard specific for the given operation. Information fusion concerning a single operation can be done using the “noisy or” gate.



Legend: Inicjator-Initiator; Zagrożenie-Risk; Spełnienie zagrożenia- Risk occurence; Inhibitor- Inhibitor; Łagodzenie skutków zagrożenia- Mitigating the effects of hazard

Fig. 1. A basic model of risk

In agreement with the European directives and related standards, the system of the risk analysis and management should enable the answering of the questions of two categories:

– risk prediction for each type of hazard.
– prediction of the most probable causes and identification of the hazard sources for each specified defect of the final product.

These questions belong to the category of the risk prediction and shall explain the reasons of the hazard. Risk management is based on the decision making in dependence on the response to the questions formulated above.

RESULTS

In this paper we apply the computer model of the process reliability of the production line to the case of dental composite materials production. In the remainder of this section we show how the model may be applied to answer specific questions on the quality of the final product.

In Fig. 2 we present a part of the Bayesian network demonstrating a predictive reasoning leading to answering the question concerning a possibility of receiving by a customer of a product that does not meet the requirements, given the probabilities of the causes of such event.

We consider the following example for the production line under consideration: Let the prior probability of using wrong pigments be equal to 2,023%, the prior probability of a dosage error be equal to 0,759%, and the prior probability of an improper mixing equals 0,670%. If the result of the strength test is positive with the probability 1,143% and the color test is negative with the probability 96,125% (the result that does not eliminate the product during the test phase), then the probability that the customer receives a defective product is equal to 10,504%.

Fig. 3 is devoted to the response of our model for a given probability that the customer receives a product not meeting the requirements, defined at an acceptable level of 0,118%. In other words, the aim of the model is to establish the maximal level of the risk of the events ”wrong pigments”, ”dosage error”, and ”improper mixing” taking place with the probabilities 0,083%, 0,009% and 0,008%, respectively, which result in the event ”wrong color” with the probability 0,049%.

In Fig. 5 we present a typical scheme of the model realization allowing for an investigation of the observed effects using the specification of the most probable causes. Assuming that the event ”the customer receives a product which does not meet the requirements” is taking place for sure (with the probability 100%), and it is due to the occurrence of the event ”wrong color” with the probability 100%, we specify the probability distributions of the network nodes preceding the node ”wrong color”:

- The wrong pigments with the probability 59,043%
- The dosage error with the probability 22,137%
- The improper mixing with the probability 19,815%.

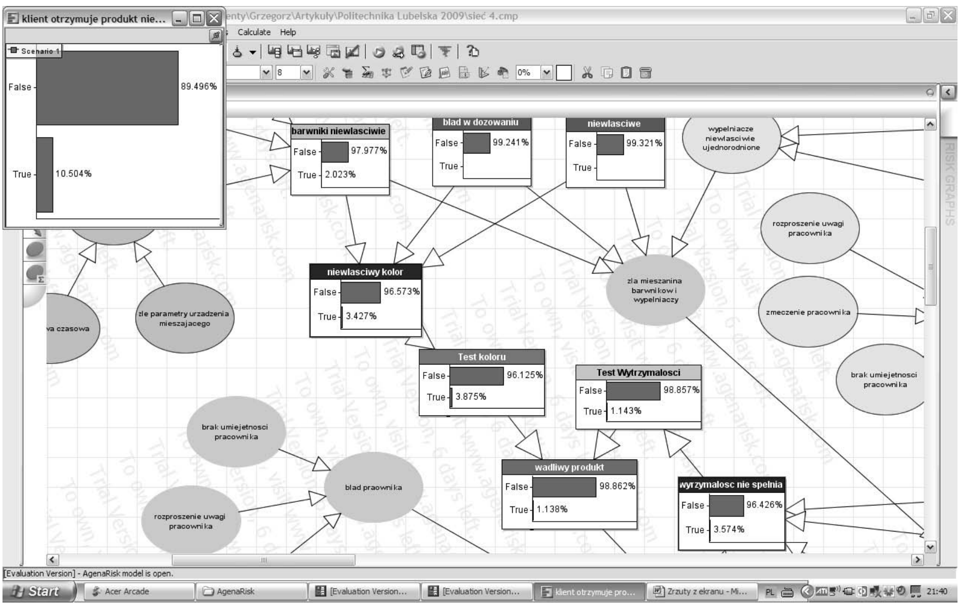


Fig. 2. Response of the network to the question about the probability of the event ”the customer receives the product which does not meet the requirements” given the probabilities of the possible causes.

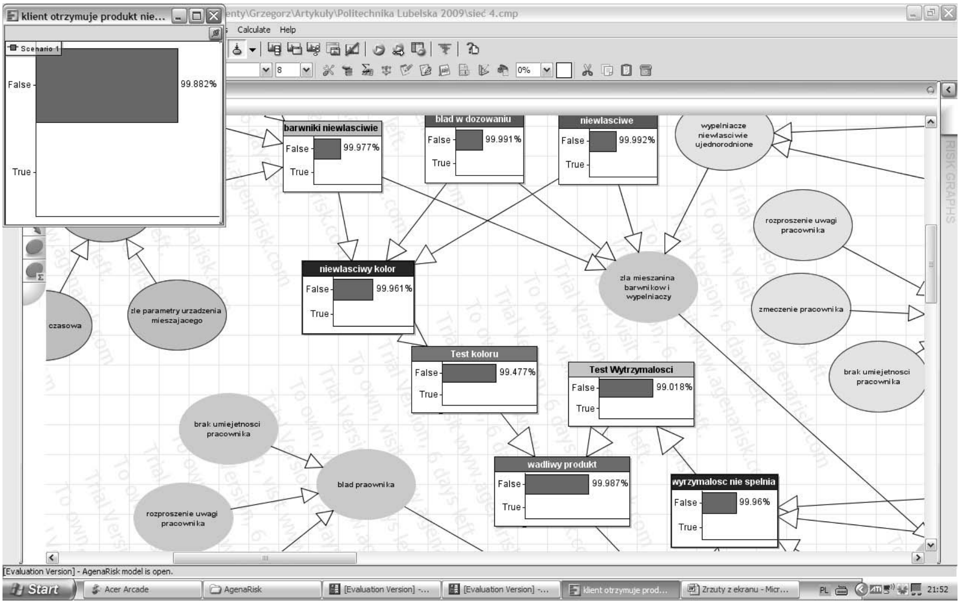


Fig. 3. Response of the network assuming a given probability of the event ”the customer receives a product which does not meet the requirements”

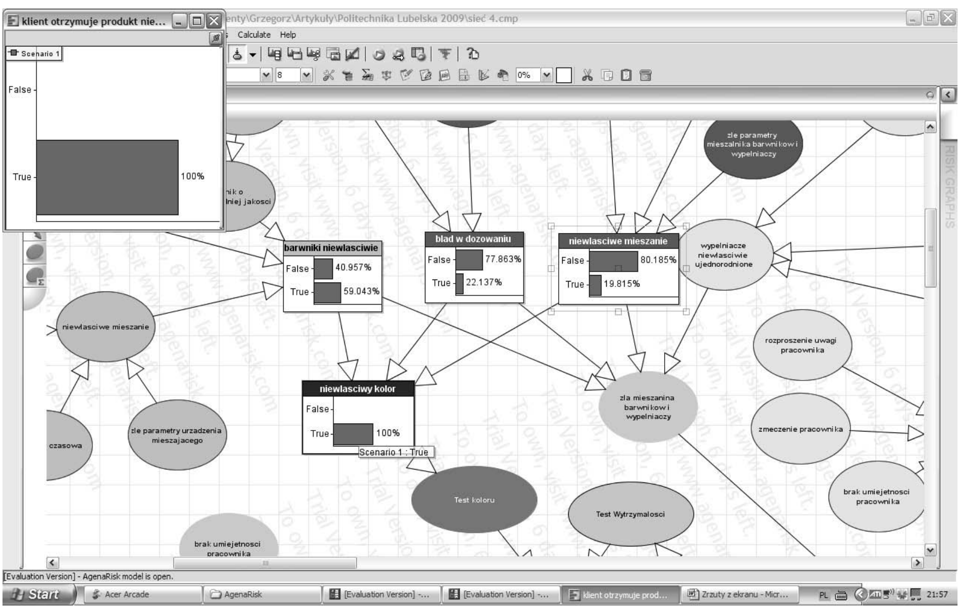


Fig. 4. Response of the network to the question about the main cause of obtaining a composite with a wrong colour given the probability of the event ”wrong color” equal to 100%.

CONCLUSIONS

The operational reliability model given in the form of the Bayesian network can be used to analyze the risk of obtaining of a final product that does not meet the requirements. Mechanisms of predictive and diagnostic reasoning typical for the Bayesian networks allow for the answering of specific questions posed in the risk analysis. In this paper we presented an example of this approach applied to the technological line of the dental composite material.

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ZASTOSOWANIE MODELU OPERACYJNO-NIEZAWODNOŚCIOWEGO W ANALIZIE RYZYKA W PROCESIE PRODUKCJI WYROBU MEDYCZNEGO

Streszczenie. Przedstawiono zastosowanie modelu tworzonego dla potrzeb analizy ryzyka przy produkcji kompozytu stomatologicznego w odpowiedzi na wymagania zarządzania ryzykiem i przeprowadzania analizy ryzyka występujące w normie ISO 13485 oraz dyrektywie MDD 93/42 dotyczących wyrobów medycznych.

Słowa kluczowe: sieci bayesowskie, analiza ryzyka, niezawodność

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THE ASSESSMENT OF THE PROCESS OF PNEUMATIC SEPARATION OF DE-HUSKED RAPESEEDS

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Summary. In this study presented is the analysis of the assessment of the process of pneumatic separation of de-husked rapeseeds in relation to the velocity of the airstream. Rapeseeds of *Kana* variety were used for the research, in which the content of the fruit-seed coat in relation to the mass of the whole seed is 18%. On the basis of the analysis of results achieved from the research conducted at five variable velocities of the airstream mixture purity, loss of endosperm, and cleaning capability were established. During the analysis of the endosperm loss and the efficiency of separation of the husk the velocity of the stream of air of... m/s (baffle XIV) turned out to be the most efficient. The efficiency of cleaning for this velocity was approx. 90%.

Key words: pneumatic separation, rape, de-husking

INTRODUCTION

Separation is the process, whose aim is to apportion from a grain mixture (input) any kind of contamination and achieve a possibly clean product (plump grain). Pneumatic separation has been mainly used for cleaning cereal in households and grain warehouses. In such places, simple separators are applied, which in their operation use one physical feature which differentiates the material from contamination, as well as complex machinery, which uses, simultaneously or sequentially, a few features, e.g.: geometric, aerodynamic, electrostatic features, features of the surface, and density [Grochowicz 1985, Modrzewski et al. 2004]. Apart from cleaning cereal this method is often used for cleaning rapeseeds, hemp and beet seeds [Mieszalski et al. 1999, Tanaś 2008, Czarnecka et al. 2008]. Special attention should be drawn to the selection of machinery which executes segregation processes and the choice of optimal parameters of these processes which are adjusted to specific materials. The principle for the segregation of a mixture of particles in a stream of air is the use of differences in their behaviour in this stream of air [Emami et al. 2007]. In pneumatic machinery horizontal, vertical and oblique streams of air are used [Oszczak 2006]. Segregation in horizontal and oblique streams of air consists in moving specific components of a mixture at various distances, depending on their aerodynamic features and density [Panasiewicz 1999, Panasiewicz et al. 2008]. Whereas in sorting-cleaning machines with a vertical stream of air a mixture is caressed by a stream which sweeps away contamination [Pastushenko et al. 2009, Reichert 1982]. Cleaned grain is directed to a bagging machine or to further units in case of a complex sorting-cleaning machine, and contamination is carried away vertically [Roz et al. 2006]. The assessment can be conducted defining the efficiency of cleaning, that is the percentage relation of the volume of contamination separated from the mass of grain to the volume of contamination in the mixture before separation [Jurga 1997].

AIM, SCOPE AND RESEARCH MATERIAL

In the presented research the research material constituted rapeseeds which underwent the process of de-husking. De-husking was carried out in a lower pole husk-sheller with a 2 mm aperture. In the research rapeseeds of *Kana* variety were used in which the content of fruit-seed coat in relation to the mass of the whole seed is 18%. The separation was conducted in a laboratory pneumatic separator (fig. 1). The principle of operation consists in feeding loose material through the inlet to the air duct where it is segregated into two fractions. It is done with the use of a fan which generates the stream of air. The intensity of the flow of the stream of air is regulated by a baffle at the cyclone.

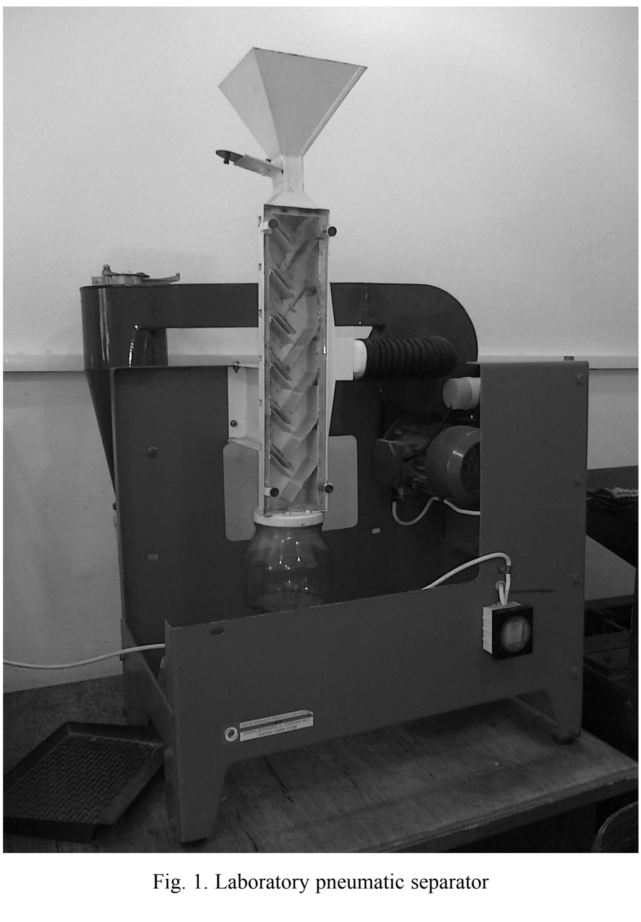

Fig. 1. Laboratory pneumatic separator

RESEARCH METHODOLOGY

The input material was directed through the inlet to the pneumatic duct. Here, with the use of the stream of air, endosperm was separated from husk. Two fractions were gathered in two separate containers which were placed after the outlets.

During the research baffles were changed from IX to XV, which corresponds to a change in the velocity of the flow of the stream of air from 6 to 10 $m \cdot s^{-1}$ in order to optimally set up the most effective choice of the intensity of the flow of the stream of air. The separated fraction with husk was once again returned to a container and the process of separation was repeated with the aim of segregating endosperm and minimising the loss of endosperm in relation to husk.

Cleanliness (the efficiency of the separation process) of the mixture was determined from the following formula [Choszcz et al. 2008]:

$$C = \frac{M}{M_c} \cdot 100 \ [\%] \qquad [1]$$

C – cleanliness of a mixture [%],
M – mass of the proper fraction in the sample [g],
M_c – total mass of a laboratory sample [g].

The process of pneumoseparation was carried out in two stages, thus for calculations cleanliness after stage I was used and marked as C I, and cleanliness after stage II was marked as C II. Whereas the overall cleanliness after two stages was marked as C I+C II.

The problem during cleaning de-husked rapeseeds is that grinded endosperm intermingles with the husk fraction (especially after the use of aspiration), which influences the efficiency of cleaning. That is why, in order to maximally separate husk from grinded endosperm, the fraction in which the major part constituted husk was cleaned.

To this end a detailed sieve analysis was used with the following set of sieves: 0; 0,1; 0,2; 0,5; 1mm.

Separated, in this way, endosperm was defined as loss and derived from the formula:

$$S = \frac{m_b}{m_c} \cdot 100 \ [\%] \qquad [2]$$

S – loss of endosperm after aspiration [%],
m_b – mass of grinded endosperm [g],
m_c – total mass of endosperm in the analysed sample [g].

The efficiency of the method for cleaning rapeseeds was defined basing on the formula:

$$\eta = \frac{M_{cz} - M_z}{M_{cz}} \cdot 100 \ [\%] \qquad [3]$$

where:

$$M_{cz} = U_z \cdot M_c \ [g] \qquad [4]$$

M_{cz} - mass of husk in the sample before cleaning [g],

M_z – mass of husk in the sample after cleaning [g],
U_z – share of husk in total of rapeseeds [g] (for *Kana* variety, U_z=0,18).

The achieved results were analysed statistically with the use of the software programme *Statistica* 6.0.

RESULTS

On the basis of the analysis of the achieved results from the research conducted at five different velocities of the flow of the stream of air, the mixture cleanliness was established, which in this case is defined as the volume of the proper fraction which went through particular separation cascades in the machinery. Results from the specific analyses are presented in fig. 2 and 3.

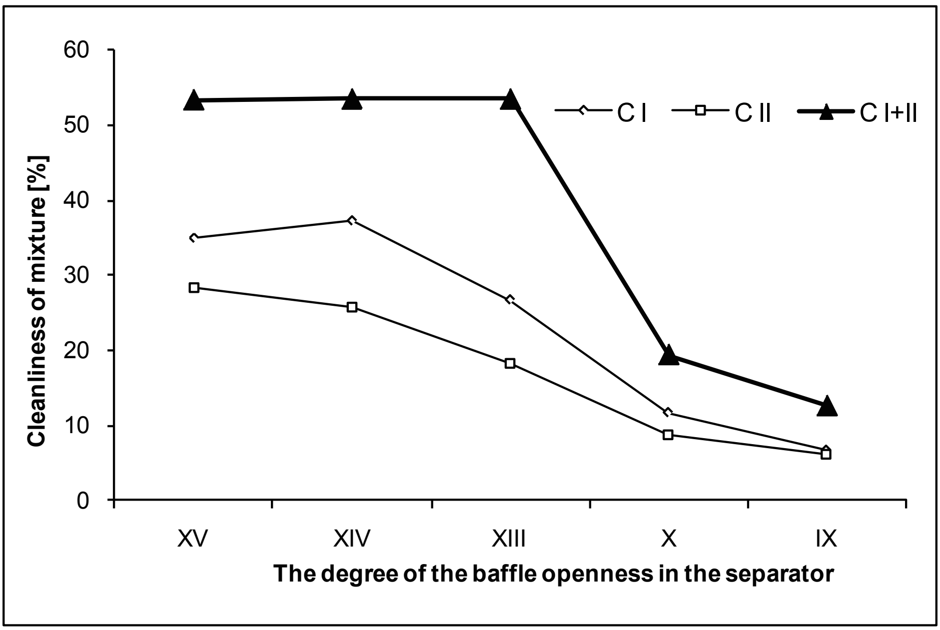

Fig. 2. Cleanliness of the mixture after stage I and II of cleaning

The cleanliness of the mixture after stage I of cleaning was not high (approx. 35% for the baffle in the position No 15), which shows big losses and low efficiency of the cleaning process. Therefore, stage II of cleaning was applied and a similar effect of cleaning was achieved, however after combining these two stages of the process cleanliness of the mixture within the range of 53% was achieved. When the velocity of the flow of the stream of air was altered the total cleanliness did not change. Only a significant increase in the velocity of the flow of the stream of air to 9 $m \cdot s^{-1}$ did cause an essential deterioration of the mixture cleanliness. For each velocity of the flow of the stream of air mixture cleanliness after stage I of cleaning was higher than after stage II. The calculation of cleanliness, efficiency and losses is presented in fig. 3.

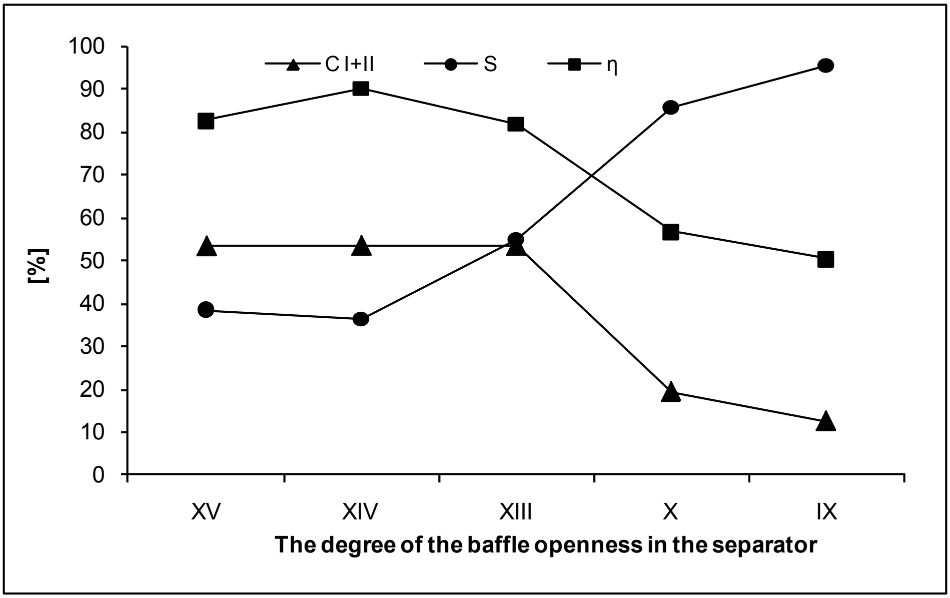

Fig. 3. The calculation of cleanliness, losses and the efficiency of pneumatic separation of de-husked rapeseeds

When analysing determined indicators of pneumatic separation of de-husked rapeseeds it can be stated that this method causes the creation of high losses in plump grain. The highest losses were recorded at the highest velocity of the flow, which exceeded even 90%. In the studied range of the flow of the stream of air the highest efficiency of separation, with losses around 36%, was achieved at the velocity 7m·s^{-1}of the flow of the stream of air. The cleanliness of the mixture was in this case approx. 50%.

CONCLUSIONS

After conducting the research the following conclusions were drawn up:

During the analysis of the results of endosperm losses and the efficiency of husk separation the most effective turned out to be the use of the velocity 7 m·s^{-1} of the flow of the stream of air (baffle XIV). The efficiency of cleaning for this velocity was approx. 90% with losses reaching approx. 36%.

The use of single separation causes low efficiency of cleaning (approx. 30%). Another stage of separation caused an increase in the efficiency of cleaning up to 50%.

An increase in the velocity of the flow of the stream of air to ... m/s (baffle X) causes a rapid decrease in the efficiency of separation, as well as an increase in losses of plump grain up to 90%.

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OCENA PROCESU SEPARACJI PNEUMATYCZNEJ OBŁUSZCZONYCH NASION RZEPAKU

Streszczenie. W pracy przedstawiono analizę ocenę procesu separacji pneumatycznej obłuszczonych nasion rzepaku w zależności od prędkości przepływu powietrza. Do badań wykorzystano nasiona rzepaku odmiany *Kana*, w których zawartość okrywy owocowo-nasiennej w stosunku do masy całego nasiona wynosi 18%. Na podstawie analizy uzyskanych wyników badań prowadzonych przy pięciu zmiennych prędkościach przepływu powietrza wyznaczono czystość mieszaniny, straty bielma oraz sprawność czyszczenia. Analizując wyniki strat bielma oraz skuteczności oddzielenia okrywy najefektowniejsze okazało się zastosowanie prędkości przepływu powietrza wynoszącej … m/s (przesłona XIV). Sprawność czyszczenia wyniosła dla tej prędkości ok. 90%.

Słowa kluczowe: separacja pneumatyczna, rzepak, obłuskiwanie

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