CIOP PIB

Market research report

Personal protective equipment for the respiratory system, eyes, face, head and hearing and medical masks

Warsaw 2021

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Information for users

CIOP PIB

Warsaw 2021

This paper is published and based on the results of a research task carried out within the scope of the fifth stage of the National Programme "Improvement of safety and working conditions" supported within the scope of state services by the Ministry of Family and Social Policy,

task no. 4.SP.24

entitled "Development of a diagnosis and forecasting trends in the development of personal and collective protective equipment market in Poland".

The Central Institute for Labour Protection - National Research Institute is the Programme's main co-ordinator

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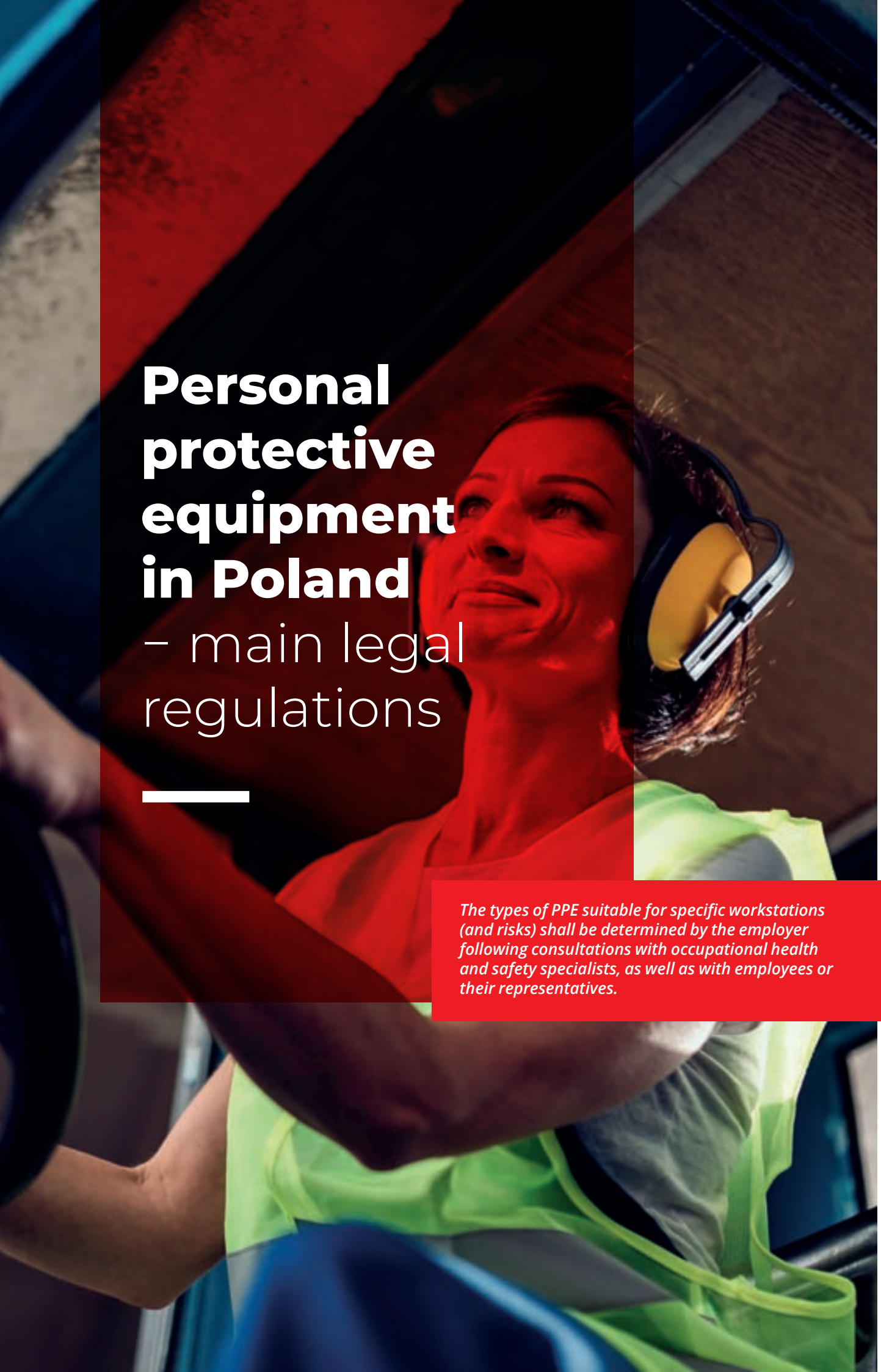


Personal protective equipment in Poland – main legal regulations

The types of PPE suitable for specific workstations (and risks) shall be determined by the employer following consultations with occupational health and safety specialists, as well as with employees or their representatives.

Personal Protective Equipment (further referred to as PPE) should be an essential element of the equipment of any employee whose work is associated with a risk to health or life.

It helps to protect employees against hazards. Employers must not allow employees to work without providing them, free of charge, with PPE necessary at a given workstation[1]. The types of PPE suitable for specific workstations (and risks) shall be determined by the employer following consultations with occupational health and safety specialists, as well as with employees or their representatives. Prior to the correct selection of such measures an occupational risk assessment should be performed.

The main provision on PPE is the Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC, which was adopted on 9 March 2016, entered into force on 21 April 2016 and is applicable from 21 April 2018. This Regulation lays down requirements for the design and manufacture of PPE and the principles of rules on the free movement of PPE in the European Union. Selected requirements and content are presented below.

Full version is available at:
https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX%3A32016R0425

[1] Act of 26 June 1974 — Labour Code, Journal of Laws 2020.0.1320

Categorisation of personal protective equipment

The equipment protecting against cuts by portable chainsaws, harmful noise and harmful biological agents, which, according to the Directive, have been so far classified as category II, is now classified as category III according to the Regulation.

Regulation (EU) 2016/425 of the European Parliament and of the Council introduced a change in the categorisation of personal protective equipment and added new risks.

The equipment protecting against cuts by portable chainsaws, harmful noise and harmful biological agents, which, according to the Directive, have been so far classified as category II, is now classified as category III according to the Regulation.

Moreover, PPE designed to prevent drowning, high-pressure jets, bullet wounds or knife stabs, are included and classified as category III. In addition, PPE providing protection against heat (for private use) which were excluded from the scope of Directive 89/686/EEC, have now been covered by the requirements of the new Regulation.

For these devices, due to the change of categorisation, there was also a change in conformity assessment procedures that are required prior to the device introduction on the EU market.

According to Regulation 2016/425, PPE is classified into 3 risk categories:

- **Category I** includes exclusively the minimal risks,
- **Category II** includes risks other than those listed in Categories I and III,
- **Category III** includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health.

Obligations of economic operators

Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the required documents and by the instructions and information set out in the Regulation, and that the manufacturer and the importer have complied with the requirements set out in the Regulation.

Regulation 2016/425 identifies the obligations of economic operators who are responsible for placing PPE on the market or making it available on the EU market.

According to the Regulation, the PPE manufacturer is responsible, inter alia, for:

- designing and manufacturing of equipment in accordance with the applicable essential health and safety requirements,
- drawing up the technical documentation and carrying out the conformity assessment procedure,
- keeping the technical documentation and the EU declaration of conformity for 10 years after the PEE has been placed on the market,
- ensuring that the PPE they place on the market is appropriately labelled,
- ensuring that the PPE is accompanied by the instructions and information,
- providing – further to a reasoned request from a competent national authority – information and documentation necessary to demonstrate the conformity of the PPE with the Regulation and cooperating with it on any action taken to eliminate the risks posed by the PPE which they have placed on the market.

The manufacturer's authorised representative shall be responsible for performing the tasks specified in the mandate received from the manufacturer.

Importers are responsible for:

- putting on the market exclusively PPE compliant with the requirements of the Regulation,
- ensuring that the PPE placed on the market have been subject to an appropriate conformity assessment procedure by the manufacturer, that the manufacturer has drawn up technical documentation, that the PPE bears the CE marking and is accompanied by the required documents,
- indicate their data on the PPE (on its packaging or in the accompanying document),
- ensuring that the PPE is accompanied by appropriate instructions and information,
- ensuring that, while the PPE is under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in the Regulation.

Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the required documents and by the instructions and information set out in the Regulation, and that the manufacturer and the importer have complied with the requirements set out in the Regulation.

Distributors shall also ensure that, while PPE is under their responsibility, its storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in the Regulation.

> In cases where the importer or distributor place PPE on the market under their name or trademark or modify the PPE already placed on the market in such a way that compliance with the Regulation may be affected, they shall be considered a manufacturer of the PPE and shall be subject to the obligations of the manufacturer.

Conformity assessment procedures

The declaration of conformity, in accordance with the Regulation, shall contain references to the conformity assessment procedures set out in the relevant modules and to the harmonised standards used, including the date of the standards, which the Directive has not clarified.

Regulation 2016/425 clarifies the rules for individual conformity assessment procedures and their nomenclature has been aligned with the rules applicable in Europe for devices other than PPE.

However, the process of individual conformity assessment procedures has not been substantially changed. Depending on the risk category that the PPE protects against, the following conformity assessment procedures are to be followed:

- Category I: internal production control (module A, Annex IV to the Regulation),
- Category II: EU-type examination (module B, Annex V to the Regulation), followed by conformity to type based on internal production control (module C, Annex VI to the Regulation),
- Category III: EU-type examination (module B), and either of the following:
  - conformity to type based on internal production control plus supervised product checks at random intervals (module C2, Annex VII to the Regulation)
  - conformity to type based on quality assurance of the production process (module D, Annex VIII to the Regulation).

EU Declaration of conformity

The declaration of conformity, in accordance with the Regulation, shall contain references to the conformity assessment procedures set out in the relevant modules and to the harmonised standards used, including the date of the standards, which the Directive has not clarified. Moreover, the new requirement is to include the information that the declaration has been drawn up on the sole responsibility of the manufacturer.

In order to ensure easy access to the declaration of conformity by the market surveillance authorities, the Regulation requires manufacturers to ensure that the PPE is accompanied by a copy of the EU declaration of conformity (the EU Declaration of Conformity should be attached to each PPE item) or by the internet address at which this document can be accessed. The declaration of conformity may also be part of the user's instructions (manufacturer's information).

Authorised representatives (where this is based on the manufacturer's power of attorney) shall keep the EU declaration of conformity at the disposal of the national market surveillance authorities for 10 years after the device has been placed on the market. A similar obligation to keep the copies of the declaration is assumed by the importers.

Labelling of personal protective equipment and manufacturer's information

Manufacturers should also indicate their name, registered trade name or registered trade mark and contact details on the PPE or its packaging or in the document accompanying the PPE.

Regulation 2016/425 requires PPE manufacturers to label each item with the type, batch or serial number or other information allowing its identification. Where the size of the PPE does not allow it, the required information should be provided on the packaging or in a document accompanying the PPE.

Manufacturers should also indicate their name, registered trade name or registered trade mark and contact details on the PPE or its packaging or in the document accompanying the PPE.

Also importers of PPE are obliged to provide their trade name or registered trade mark, and postal address on the PPE or its packaging, or in the document accompanying the PPE.

The CE marking shall be affixed visibly, legibly and indelibly to the PPE. The requirement for affixing next to the CE marking of the number of the notified body involved in the conformity assessment procedure in accordance with module C2 or D, which was included in the Regulation, was maintained.

Personal protective equipment and medical masks market research

The study attempted to identify entities involved in both the manufacture and distribution of PPE and medical masks (they are described in the supplement to the study, which can be ordered at CIOP-PIB).

In view of the very dynamic development of the PPE and medical masks market caused by the COVID-19 pandemic, due to the unquestionable need to analyse this market both in terms of the needs of manufacturers and distributors, and the introduction of innovation by research institutions involved in the development of this equipment, a market research study was conducted.

The need for this study was also due to the lack of such analyses on the Polish market. The reasons for the lack of such studies can be considered, among others, in the context of the dynamics of economic changes in Poland, rapid technological development of PPE and the impact of globalisation and the activity of the Far East countries to supply the global market with this equipment.

The demand for such a study, expressed in bilateral discussions with manufacturers and their associations, confirmed the findings of the Institute's employees in this regard. Therefore, it can be assumed that this report will help to facilitate the market entry of new entities and increase competitiveness.

The study attempted to identify entities involved in both the manufacture and distribution of PPE and medical masks (they are described in the supplement to the study, which can be ordered at CIOP-PIB).

Based on the techniques described in the next section, this paper presents the key findings of the study relating to the PPE and medical masks.

Detailed results containing information on the current and anticipated situation of suppliers, the current and future demand of customers, market competition, barriers to entry and key elements of the supply chain, as well as the development directions for the PPE and medical masks market, in particular those intended for suppliers (importers, manufacturers, authorised representatives and distributors), are available on demand at the Central Institute for Labour Protection – National Research Institute.

Study objective, scope and methodology

The report was drawn up using a diverse set of research methods and techniques and data sources employed in accordance with the methodological triangulation concept.

The aim of the study was to provide information on the Polish market of suppliers of PPE and medical masks – both importers and manufacturers, as well as their authorised representatives and distributors of PPE for the eyes, face, head, hearing, respiratory system, and of medical masks. It was also important to identify and analyse not only the supply, but also the demand, i.e. recipients of PPE and medical masks.

Based on this identification, an attempt was made to analyse the market and project trends – directions for further development of this market.

The study sought to answer the following questions:

1. **Which suppliers (importers, manufacturers, authorised representatives and distributors)** of PPE and medical masks can be identified on the Polish market and what are their characteristics?

2. **What level of competitiveness and concentration characterises** this market in Poland (currently and in the near future)?

3. **What is the size and value of the production and sales volume of the above-mentioned PPE in Poland** (for entities with significant market share) and what factors influence the prices?

4. **What are the market entry barriers and the key elements of the supply chain** (taking into account domestic and foreign intermediates manufacturers)?

5. **Which recipients of PPE and medical masks** can be identified?

6. **What factors affect the demand for the** above-mentioned devices?

7. **What is the innovative potential of the market and what environmental factors** affect the behaviour of the suppliers and recipients of PPE and medical masks**?**

8. **What recommendations can be made to suppliers, market surveillance authorities and other regulatory entities,** to units developing PPE solutions, representatives of employers responsible for providing PPE in enterprises, and direct users of PPE and medical masks?

The report was drawn up using a diverse set of research methods and techniques and data sources employed in accordance with the methodological triangulation concept.

The study involved:

- **Desk research,** which was used to review legal acts, statistical data, databases of certification and control institutions, financial reports of companies, as well as industry studies and articles. An important element of the analysis was the development of a basic database of suppliers operating on the Polish market of PPE and medical masks, which includes not only contact details of the entities, but also information on the type of PPE manufactured/ distributed.
- **Mixed-mode questionnaire survey (quantitative study) (**CATI/CAWI) performed on a nationwide sample of representatives of PPE and medical mask suppliers and recipients. The study used the non-random sampling technique proportional to the number of economic entities present in a given province, according to the Statistical ID Number (REGON) database, taking into account the size of enterprises. A total of 204 respondents took part in the quantitative study:

	PPE recipients			PPE suppliers	Medical mask suppliers
Size of enterprise	10-49	>50	Total		
Sample size	36	18	54	100	50

Source: Grupa BST Sp. z o.o. study

- **In-depth expert interviews (qualitative study)** aimed to clarify/confirm the information obtained in the CATI/CAWI quantitative study. The qualitative study involved 20 experts, namely, representatives of suppliers and recipients, including representatives of the occupational health and safety services or occupational health and safety professionals outside of the workplace, a representative of the market surveillance authority and representatives of the R&D environment developing PPE solutions.

Based on the above-mentioned techniques, the main results of the study are presented below.

Characteristics of personal protective equipment suppliers

When analysing distribution channels of the offered product range, the PPE suppliers sell their products both in traditional and online stores, while every fourth supplier (26%) sells their products online only.

In addition to the desk research, the results of quantitative and qualitative studies were used to characterise the market of PPE and medical mask suppliers.

100 interviews were conducted with PPE suppliers, and 50 interviews were conducted with the medical mask suppliers. The survey included respondents from all over the country, and the number of surveyed entities from a given province was proportional to the number of economic entities in this area. The data was obtained from the Statistical ID Number (REGON) database.

In a questionnaire survey conducted with the PPE suppliers, 42% of the surveyed entities were manufacturers, while 64% were distributors, authorised representatives or importers.

Small- and medium-sized enterprises, employing up to 49 people (79%), predominated among the surveyed PPE suppliers. 21% of the surveyed companies employed more than 50 people, including 1% employing over 250 people. This indicates a relatively large fragmentation of the Polish supplier market.

> The vast majority (90%) of the surveyed companies operated on the PPE market for at least 5 years, with none of the companies operating for less than 1 year.

Some of the participants have been working in the PPE industry for several decades (30 years or more).

The population of respondents also included representatives of companies present on the market for relatively long periods (several, sometimes ten to twenty years), which launched the manufacture of personal protective equipment only in 2020. A change of the industry or business expansion undoubtedly result from the outbreak of the pandemic and from the increased demand for PPE.

For the majority (61%) of the suppliers surveyed, PPE for the eyes and face, head, hearing and respiratory system accounted for at least 25% of the total manufacturing/distribution offer of the company. It thus follows that companies operating in various areas have expanded their manufacturing/distribution offer or switched to the PPE manufacturing/distribution due to the increased market demand for this product range.

Manufacturing /Distribution

According to the PKD (Polish Classification of Activity) codes, the principal activity of the surveyed entities distributing PPE (36 out of 74 entities for which financial data for 2020 on net sales and profits was possible to collect for the purposes this study) was the sale of clothing and footwear, followed by non-specialised sales.

When analysing distribution channels of the offered product range, the PPE suppliers sell their products both in traditional and online stores, while every fourth supplier (26%) sells their products online only. This is certainly the result of technological development but also of the COVID-19 pandemic and the need to reduce direct contact.

Competition

Every other surveyed supplier (55%) indicated that the number of the most serious competitors in the PPE market did not exceed three.

It can be concluded from the in-depth interviews with PPE suppliers that the most important competitors include companies with an established market position, which have operated in the industry for many years. However, the interviewed experts pointed out that a large number of ad hoc companies are entering the market due to the increasing pandemic-driven demand for PPE.

> According to some suppliers with many years of experience, the market in their industry has considerably increased since 2020. Previously, they have been dealing with about 3–4 competitors in their area for years.

Characteristics of medical mask suppliers

According to the surveyed recipients of PPE and medical masks, mass vaccination against COVID-19 and a reduced number of cases (at the time immediately preceding the survey) caused a certain stabilisation on the market.

When characterising the suppliers of medical masks, it is worth noting the difference between medical masks, classified as a medical device, and protective masks which are PPE.

A medical mask is a medical device constituting a barrier that minimises the direct transmission of infectious agents between the staff and the patient (it is not PPE).

A medical mask should bear CE marking and should conform with:

- the 'PN EN 14683+AC:2019 Medical face masks – Requirements and test methods' standard
- the declaration of conformity with the requirements of the Regulation of the Minister of Health of 17 February 2016 on essential requirements and the procedures for the assessment of conformity of medical devices (Journal of Laws, item 211) or the declaration of conformity with the requirements of Directive 93/42/EEC, or declaration of conformity with the requirements of Regulation (EU) 2017/745.

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices in Annex 1, section 8.1, specifies that medical devices must satisfy the microbiological purity criteria.

The entities placing the masks intended for use as medical devices on the market are obliged to notify the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL). The notification to the URPL should indicate that the device is a class I medical device manufactured in accordance with rule 1. The market surveillance authority may check compliance with this requirement.

Moreover, the entities placing the masks classified as medical devices on the market in Poland are obliged to notify and register. This guarantees the President of URPL a possibility to identify the marketed products and entities responsible for their placement on the market, as well as a possibility to verify that they meet the required safety quality standards.

In connection with the outbreak of COVID-19 pandemic, on 9 April 2020, the guidelines of the national infectious disease consultant were published in Poland, specifying what conditions should be met by a product defined as a medical mask. According to the guidelines, a medical mask is a product with protective features, protecting against biological agents, which should:

- comply with the requirements of the EN14683 standard:
  - → Bacterial Filtration Efficiency (BFE) (%) as for type II or IIR masks,
  - → Airflow resistance (Pa/cm2) as for type II or IIR masks,
  - → Biostaticity (maintaining microbiological purity), or be made of material that meets the above requirements,
- be made of a three-layer cloth,
- be tied at the back with straps or have an elastic band that allows the user to put the mask on their ears,
- have pleads in the middle section to adjust the mask to the face shape – cover the nose, lips and chin,
- have a strengthening element along one of the edges to adjust the mask to the nose, thus ensuring additional possibility to adjust it to the wearer's face,
- have the dimensions of at least 17.5 cm x 9 cm (when measured "flat").

In the questionnaire survey of the suppliers of medical masks, the majority of respondents represented medical masks manufacturers (78%) and distributors. 8% of respondents indicated two answers, which means they are both manufacturers and distributors of medical masks.

According to the surveyed recipients of PPE and medical masks, mass vaccination against COVID-19 and a reduced number of cases (at the time immediately preceding the survey) caused a certain stabilisation on the market.

The vast majority (86%) of the surveyed suppliers of medical masks has been operating on the market for more than 5 years, but every tenth company (10%) has been running business for up to 3 years.

As many as 84% of medical mask suppliers are companies employing fewer than 49 people.

For the vast majority (68%) of companies supplying medical masks, the revenue from their sales constitutes up to 25% of the company's revenues, which is indicative of the diversification of activities and revenues of companies on the Polish market. 75% suppliers of medical masks use the Internet as a sales channel, including 19% who sell exclusively online.

Among the surveyed manufacturers of medical masks, the vast majority

80%

declared that they had started production in connection to the outbreak of the COVID-19 pandemic.

During the study period (Q3 2021) slightly more than a half

57%

of the surveyed manufacturers continued to produce medical masks

21%

were not planning to produce medical masks within the next five years

Characteristics of personal protective equipment and medical masks recipients

The recipients of PPE indicated that the demand for this range of products is primarily affected by the obligation resulting from legal regulations (94% of answers). This factor was also indicated as key by the interviewed experts.

In a questionnaire survey of the recipients of PPE and medical masks, respondents represented business entities from all Polish provinces, employing at least 10 people. In order to obtain information from recipients making significant purchases from each province, at least one company employing more than 50 people participated in the survey.

Among the surveyed recipients of PPE and medical masks, a vast group (67%) were companies employing up to 49 people. The respondents represented both the private and the public sector.

When answering the question on who is responsible for the purchase of PPE in the company, only 13% of the surveyed recipients indicated that it was occupational health and safety professionals. Most frequently the purchases were done by other employees.

Entities obliged to comply with the Public Procurement Law, such as budget entities or local government units, independent public healthcare institutions or public universities which decide to purchase PPE or medical masks, must select them and conduct the purchase procedure in a strictly defined manner. Due to the requirement to conduct a tender procedure for the purchase of PPE by such entities (the representatives of which participated in in-depth interviews), a committee is established, composed of specialists in specific fields as well, knowing the nature of the workplace and the required protective equipment. The committee also includes persons not involved in occupational safety issues or who are not acquainted with the nature of work at a given position, but are responsible for conducting the purchase procedure as required by law. This may to some extent explain the above-mentioned results of the questionnaire survey.

Selection of the product range under public procurement law requires the determination of appropriate parameters to be taken into account when selecting a supplier. The persons participating in in-depth interviews — and participating in such procedures — stated that some of the important selection criteria are the quality of the product (compliance with the legal requirements, having the necessary certificates and approvals) and the delivery dates (the shorter, the better), but also the price, which is often the main choice criterion. Tender procedures prevent the selection of a supplier (manufacturer/distributor) based on favourable experience of cooperation with this entity.

Our research shows that the offer of PPE suppliers meets the customers' demand. Among the surveyed suppliers of PPE, 76% offered respiratory protective equipment, and 69% offered eye and face protective equipment. Every other surveyed company supplied head (51%) and hearing (49%) protective equipment.

The recipients of PPE indicated that the demand for this range of products is primarily affected by the obligation resulting from legal regulations (94% of answers). This factor was also indicated as key by the interviewed experts.

Similarly, the most important reason for the purchase of medical masks seem to be legal requirements. The surveyed medical masks recipients purchase them for their employees mainly to ensure compliance with the existing obligation to cover the face and nose. Only 4% of respondents declared that the purchase of medical masks for their employees does not result from the obligation to cover the face and nose. It is worth noting, however, that the purchase of medical masks for the company customers is not a common practice. Such purchases are made by fewer than one in ten surveyed companies (9%).

These industries are at the same time most frequently targeted by the PPE suppliers. According to the study, the offer of the majority (72%) of the surveyed PPE suppliers is addressed to the manufacturing industry. Slightly fewer entities are targeting the construction (66%) and the healthcare industry (58%).

A vast majority (80%) of the PPE suppliers in Poland offer their products nationwide, while 33% address it also to foreign recipients.

The PPE suppliers most frequently indicated that micro- and small-sized companies contribute to their highest sales revenues (58% of answers). The revenue generated from the purchases made by individuals was more frequently indicated by the surveyed companies as bringing the highest sales revenue than the purchases made by companies employing more than 250 people (8% and 5%, respectively).

The surveyed medical mask suppliers most often reported that their company's largest income is generated by the sale of medical masks for the business sector (38% of answers).

91%

The vast majority of the surveyed recipients of PPE reported purchasing of respiratory protective equipment, almost half

48%

of eye and face protective equipment

Industries most represented by the surveyed PPE and medical masks recipients are

48%

manufacturing

35%

construction

The innovative potential of the market of personal protective equipment and medical masks

30% of PPE suppliers have declared that they had introduced innovations in the last 3 years. Medical mask suppliers, in turn, have shown a much lower level of innovation in recent years.

Research shows that the PPE market has a high innovative potential, but there are important factors that interfere with its development (as mentioned by the experts during in-depth interviews — both by the suppliers and the occupational health and safety specialists, and the representatives of the R&D community).

According to the experts, the enterprises are motivated to undertake actions involving the introduction of innovations by profit. Not only do the companies have their own R&D departments, but they also engage in cooperation with research and scientific institutions.

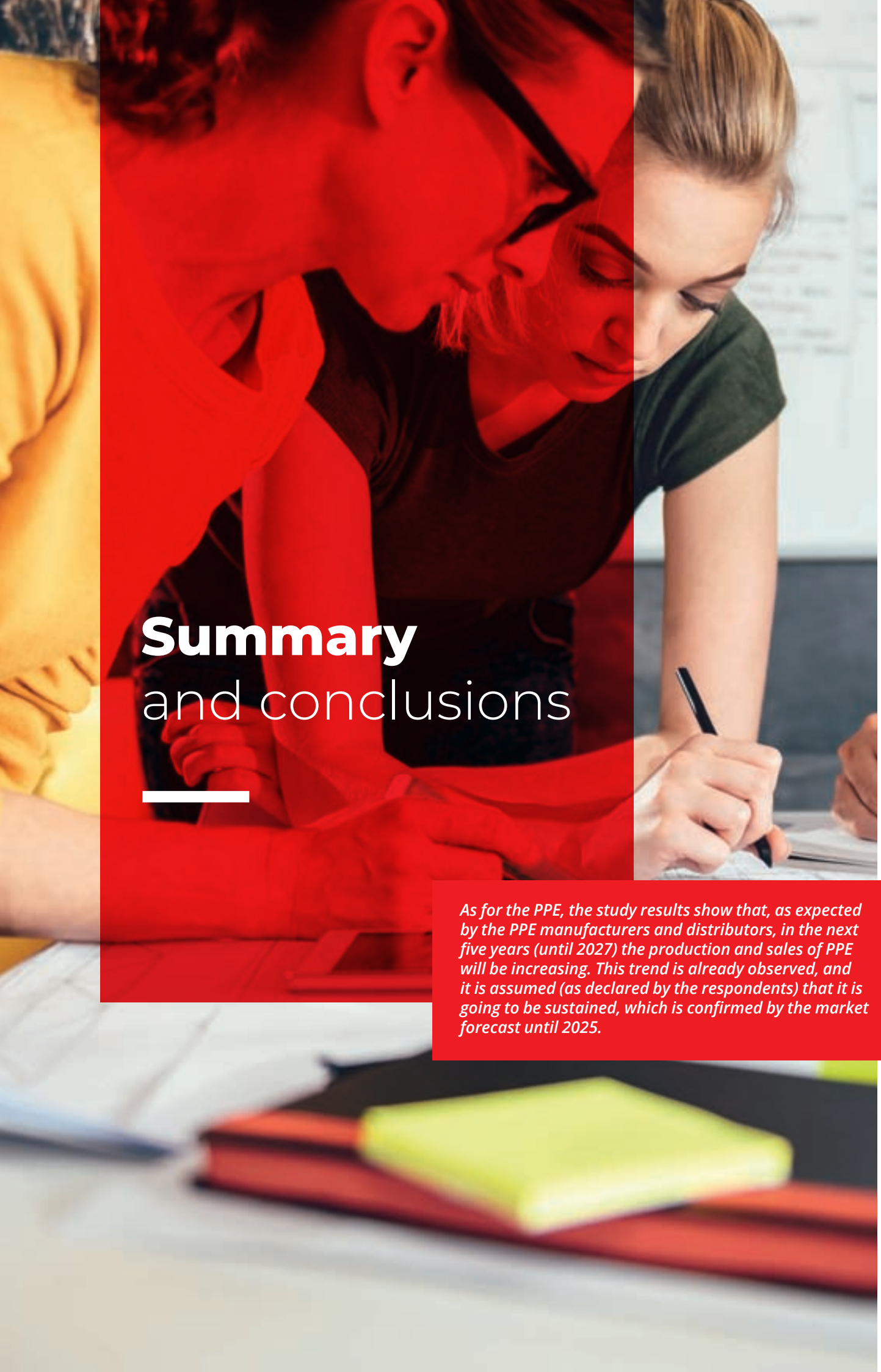
The experts point out that the innovative potential of the PPE market is mainly found in large heritage brands. For the younger companies on the market, innovations are more difficult to introduce due to the necessity to cover their costs.

The research identified factors limiting the introduction of innovations by the PPE suppliers, such as:

- existing legal requirements, costs of certificates, need for product certification;
- the Public Procurement Act (the frequently applicable criteria include product compliance with the regulations, price and supply, while innovation is rarely taken into account);
- the costs of conducting research;
- the time-consuming nature of research;
- the supply of intermediates needed to manufacture a new product;
- lack of funds for innovation;
- lack of funds from recipients to purchase innovative products (resulting from the tender procedure);
- high price of the innovative product which may result in a reduced demand for the product;
- lack of internal company laboratories, which means that in order to verify an innovative product, manufacturers have to await the results from accredited laboratories;
- customer habits.

Although the interviewed experts estimated that the innovative potential of the PPE market is high, for recipients, the innovative nature of the product is not a determining factor when it comes to purchase (although there are also companies for which product innovation is important).

30% of PPE suppliers have declared that they had introduced innovations in the last 3 years. Medical mask suppliers, in turn, have shown a much lower level of innovation in recent years. Only 14% of these entities engaged in innovative activities. The PPE and medical mask supplier reports show that the level of innovation may actually decline in the future (from 14% to 2% and from 30% to 21%, respectively).



Summary and conclusions

As for the PPE, the study results show that, as expected by the PPE manufacturers and distributors, in the next five years (until 2027) the production and sales of PPE will be increasing. This trend is already observed, and it is assumed (as declared by the respondents) that it is going to be sustained, which is confirmed by the market forecast until 2025.

The analysis of the studies (quantitative and qualitative) and of the desk research results provided data on:

- suppliers (importers, manufacturers, authorised representatives and distributors) and recipients of PPE and medical masks that can be identified on the Polish market
- current and future level of competition and concentration of the PPE and medical masks market in Poland
- volume and value of production and sale of the above-mentioned devices in Poland
- price-shaping factors
- market entry barriers and key elements of the supply chain
- factors influencing the demand for the above-mentioned devices
- market innovation potential and factors influencing the behaviour of suppliers and recipients.

Some of the above-mentioned data and their interpretation are presented in this report.

Detailed research results are available in the supplement to this report and include:
- the current and projected situation of the suppliers of PPE and medical masks
- current and future demand of recipients for PPE and medical masks
- competition on the PPE and medical masks market
- entry barriers to the PPE and medical masks market, and key elements of the supply chain
- further development directions of the PPE and medical masks market.

In particular, these results are intended for suppliers (importers, manufacturers, their authorised representatives and distributors) and are available for purchase upon order at the Central Institute for Labour Protection – the National Research Institute (the payable part is intended, among others, for potential investors).

Based on the conducted research, an analysis was performed of the existing market of PPE used in the work environment (for protection of the employees' eyes, face, head, hearing and respiratory systems), and due to the ongoing COVID-19 pandemic, of the medical masks market. Conclusions that can be used by the recipients of the above-mentioned equipment and entrepreneurs (both suppliers and distributors) were also presented. They can contribute to the potential growth of innovation of the designed products as well as allow companies to perform independent market analyses. The conclusions from the presented studies can be divided into two major sections:

1. section on the market of PPE for the protection of the employees' eyes, face, head, hearing and respiratory system
2. section on the market of medical masks the use of which increased dramatically during the COVID-19 pandemic.

As for the PPE, the study results show that, as expected by the PPE manufacturers and distributors, in the next five years (until 2027) the production and sales of PPE will be increasing. This trend is already observed, and it is assumed (as declared by the respondents) that it is going to be sustained, which is confirmed by the market forecast until 2025.

Back in 2018, Transparency Market Research (TMR) published a report informing that the PPE market was growing at a very fast pace due to the global development of industry and sectors such as transport, manufacturing and construction. This global tendency mentioned in the TMR report is also reflected on a national scale: the above-mentioned questionnaire survey showed that approximately 70% of the surveyed PPE suppliers offer their products to the manufacturing and construction industries, while approximately 60% to the healthcare industry.

Thus, the demand for PPE has increased in recent years and it is expected to continue to increase. However, the expected growth of PPE production and sales is influenced, among other factors, by the introduction of shorter supply chains. This is undoubtedly due to the PPE suppliers' experience of the supply chains disruption back in 2020/2021, which triggered a change in their approaches.

The research described in this report shows that PPE and medical mask suppliers use both foreign and domestic suppliers of intermediates. Although they experienced problems related to delays in the delivery of intermediates, the rising prices of raw materials and transport mean that Polish suppliers will look for domestic suppliers of intermediates who offer good prices.

One undoubtedly positive effect of the pandemic was the increase in knowledge and social awareness of the use of not only medical masks, but also of PPE in the workplace. When asked about the factors that have had a favourable influence on the development of the PPE market, the respondents mainly mentioned the increased awareness (of both employees and employers, as well as of policy-makers) of the role of PPE in ensuring occupational health and safety in the workplace.

In addition, the development of the PPE market has undoubtedly translated into financial benefits for manufacturers and distributors.

> In a questionnaire survey, approximately 70% of the suppliers rated the current financial situation of their company as favourable.

The suppliers of medical masks assessed their financial situation favourably as well. Also, nearly 70% of medical mask suppliers indicated that the financial situation of their companies had improved.

One of the significant changes in the market, confirmed in research, is the growing role of the Internet as a distribution channel of PPE and medical masks. The outbreak of the COVID-19 pandemic has undoubtedly resulted in the development of information technologies to popularise this method of distribution. Every fourth PPE supplier reported selling their products solely online.

> In the opinion of suppliers, the vast majority of recipients of their products (almost 80%) are most willing to buy in online stores. In the case of the medical mask market, over 80% of respondents declared selling their product range via the Internet.

The possibility of online distribution, in addition to streamlining and accelerating the sales process, also opens the door to dishonest suppliers who use it to trade in equipment which does not meet the regulatory standards. Due to the possibility of such infringements of law, the Office of Competition and Consumer Protection (UOKiK) plays an important role by monitoring the market and responding to irregularities, e.g. by submitting notifications on the detection of dangerous products in the European Rapid Exchange of Information System (RAPEX).

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Market research report

ISBN 978-83-7373-363-3

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