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EFFECTS OF THE COVID-19 PANDEMIC ON THE NOTIFICATION OF PROTECTIVE MASKS TO THE RAPEX SYSTEM

Joanna Wierzowiecka[1]*, Victoria Dąbrowska[2]

[1,2] Gdynia Maritime University, Faculty of Management and Quality Science, 81-87 Morska St., 81-225 Gdynia, Poland

[1] ORCID 0000-0003-4710-7350, e-mail: j.wierzowiecka@wznj.umg.edu.pl

*Corresponding author

Abstract: The aim of the study is to assess the notification of protective masks to the RAPEX system. The coercion to wear protective masks at the beginning of the CoViD-19 pandemic led to significant, unexpected demand for these products. The sudden increase in demand caused an initial lack of availability of the masks for consumers but their supply to the market subsequently increased. At the same time, market surveillance authorities detected a significant number of cases of non-compliance as a result of numerous checks. The impact of the CoViD-19 pandemic on the number and types of notifications for protective masks to the EU's system for the rapid exchange of information on dangerous non-food products (RAPEX) was examined. Based on the results, the conclusion is that the CoViD-19 pandemic had a significant impact on the number of notifications regarding protective masks. The assumption regarding the country of origin of the notified masks was also confirmed, as the highest number of notifications concerning protective masks originating in China were notified to RAPEX in 2020, 2021 and 2022. Germany and Belgium were the countries giving notifications for these products.

Keywords: protective masks, RAPEX system, CoViD-19 pandemic, dangerous products, China.

1. INTRODUCTION

CoViD-19, a severe infectious disease caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus, was first detected in the Chinese city of Wuhan. Due to its high infectivity, it spread on a global scale [Verity et al. 2020]. Indeed, it was described as one of the most serious global health disasters in human history, leading to huge decreases in the population as well as many economic changes [Yu et al. 2021]. Overnight, it changed the life of almost every human being. The sanitary regime, the increase in unemployment, constrained mobility and even the lack of travel opportunities entailed further consequences. People who had the opportunity to work remotely performed their work duties from home, limiting

contacts with other people to a minimum [Coibion, Gorodnichenko and Weber 2020]. It is worth noting, however, that a significant part of professions cannot work under this regime. Moreover, they are heavily dependent on interpersonal contacts. The most vulnerable were health care workers who put their lives and health at risk to care for patients. The beginning of the pandemic was associated with a lack of vaccines and significantly limited resources of personal protective equipment (PPE).

The sudden increase in demand for this type of products led to difficulties in supply chains. Neither manufacturing nor logistics companies were prepared for such immediate changes. It was important to first provide the necessary PPE for hospitals and healthcare facilities [Blau, Koebe and Meyerhofer 2021]. Accordingly, the European Commission gave certain recommendations for improvements in this area [Zalecenie Komisji (UE) 2020/403]. Nevertheless, it is important for PPE emerging on the market to comply with European requirements regarding its safety, which is controlled by the relevant supervisory authorities of the Member States. Information on products posing a serious risk to the health and safety of consumers is included in the EU's Rapid Alert System for Dangerous Non-food Products (RAPEX) [Muss and Lesiów 2018; Pigłowski 2018; European Commission 2023]. Protective masks, which played a significant role during the CoViD-19 epidemic. are among the PPE reported to this system.

In this context, the following research questions were raised:

1. Did the CoViD-19 pandemic affect the number of notifications of protective masks in RAPEX?
2. Which country sent the most notifications of protective masks to RAPEX between 2020 and 2022?
3. What was the country of origin of the largest number of protective masks notified to RAPEX between 2020 and 2022?

The aim of the study is to determine the impact of the CoViD-19 pandemic on the appearance of non-conforming protective masks on the EU market based on the analysis of the number and types of notifications for protective masks to RAPEX.

The subject of PPE, especially protective masks, is still relevant today, despite the lifting of most restrictions. Because CoViD-19 was a new threat, notifications of protective masks to RAPEX have not as yet been analysed.

2. EUROPEAN REQUIREMENTS FOR PROTECTIVE MASKS

PPE are devices manufactured to protect the health and safety of persons using them. These products are covered by the Community harmonisation legislation providing for the affixing of the "CE" mark on such items in accordance with Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products [Rozporządzenie Parlamentu Europejskiego i Rady (WE) 765/2008].

PPE may be placed on the market after meeting the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on PPE and provided that they do not pose a risk to people, pets and property when used correctly. The requirements for these products are determined based on the classification of PPE, taking into account risks that PPE is supposed to counteract. The essential requirements set out in the above-mentioned Regulation are mandatory and apply to all PPE [Rozporządzenie Parlamentu Europejskiego i Rady (UE) 2016/425].

Regulation 2016/425 also specifies additional requirements for various types of PPE, including filtering half masks, i.e. protective masks, which are face masks designed to protect against solid particles and aerosols. Filtering half masks are subject to requirements concerning, among others, the adjustment system, sweat reduction, speed of putting on and taking off or the use of identification marks. There are also requirements specific to individual hazard types. In the case of protective masks, they provide protection against substances and mixtures dangerous to health and against harmful biological agents, particularly important in the aspect of the CoViD-19 pandemic [Rozporządzenie Parlamentu Europejskiego i Rady (EU) 2016/425; Brochocka, Pośniak and Skowroń 2018].

EN 149:2001+A1:2009 (Respiratory protective devices – Filtering half masks for protection against particles – Requirements, testing and marking) is the standard harmonised with Regulation 2016/425, applicable to filtering half masks. Filtering half masks are classified according to their filtration efficiency and the total internal leakage. Thus, we have the following half mask types:

- FFP1 (80% efficiency in retaining particles of harmful aerosols sized 300 nm and larger);
- FFP2 (94% efficiency in retaining harmful aerosol particles sized 300 nm and larger);
- FFP3 (99% efficiency in retaining harmful aerosol particles sized 300 nm and larger) [Majchrzycka, Pośniak and Górny 2020].

Medical masks, on the other hand, are medical devices that cover the mouth and nose and constitute a barrier that minimises the direct transmission of infectious agents between staff and the patient. Wearing medical masks is also recommended to reduce the risk of spreading infection, especially during an epidemic or pandemic [European Centre for Disease Prevention and Control 2020]. Medical masks are subject to the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. The harmonised standard is EN 14683:2019+AC:2019 (Medical masks – Requirements and test methods), the compliance with which is the basis for determining compliance with Regulation 2017/745 [Rubio-Romero et al. 2020]. However, non-conforming medical devices falling within the scope of Regulation (EU) 2017/745 are not covered by RAPEX.

3. THE EUROPEAN SYSTEM FOR THE RAPID EXCHANGE OF INFORMATION ON DANGEROUS PRODUCTS (RAPEX)

RAPEX is the EU's system for the rapid exchange of information on dangerous products, which was established by Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, hereinafter referred to as the General Product Safety Directive (GPSD [Dyrektywa 2001/95/WE)). The aim of this system is the rapid exchange of information between the Member States and the European Commission. This information involves measures and actions taken in respect of products that endanger the health or safety of consumers [Neza and Centini 2016].

According to the applicable Act of 12 December 2003 on general product safety, implementing the GPSD in Poland, a safe product is a product which, under normal or foreseeable conditions, taking into account the duration of use of the product and depending on the type of product, the way in which it is put into service and the requirements of installation and maintenance, does not present any risk to consumers or, at most, presents a minimum risk compatible with normal use, taking into account the high level of requirements for the protection of human life and health [Dyrektywa 2001/95/WE; Ustawa z dnia 12 grudnia 2003].

The scope of RAPEX includes products subject to the GPSD, i.e. consumer products, as well as products to which Regulation (EC) 765/2008 of the European Parliament and of the Council lays down requirements for accreditation and market surveillance relating to the marketing of products applies [Rozporządzenie Parlamentu Europejskiego i Rady (WE) 765/2008]. Consumer products include products intended for consumers and "migratory" products, i.e. those that have been produced with the intention of professional use but are available for purchase by all consumers. By contrast, products covered by Regulation (EC) No 765/2008 are intended both for consumers and for professionals. The inclusion of products covered by Regulation 765/2008 in the scope of RAPEX extends the area of risks; not only risks relating to the health and safety of consumers have been taken into account, but also other types of risk including environmental risks [Ene 2011].

The guidelines for the management of RAPEX and its notification system are currently governed by Commission Implementing Decision (EU) 2019/417 of 8 November 2018, which replaced Commission Decision (2010/15/EU) of 16 December 2009. The existing guidelines set out the reporting mechanisms and related processes, criteria, forms and data required as part of the notification. They also specify timelines for specific actions and methods for risk assessment, with a particular focus on serious risks [Decyzja wykonawcza Komisji (UE) 2019/417].

The guidelines define and categorise the coercive and voluntary measures taken by companies placing or distributing dangerous products on the market. Compulsory measures are taken following an order given by relevant authorities of a Member

State, while voluntary measures are taken by manufacturers and/or distributors responsible for products [Vincze, Dahouk and Dieckmann 2019].

The RAPEX system plays an important role in guaranteeing safety of products at the national and EU levels. The data contained in the system is particularly helpful in preventing the marketing of products presenting a risk. They enable ongoing monitoring of the effectiveness of market surveillance activities together with all activities undertaken by the authorities of the Member States in the area of compliance control [Song et al. 2013].

Member States send notifications to RAPEX where emergency measures are required pursuant to art. 11 or art. 12 of the GPSD and art. 22 or art. 23 of Regulation (EC) 765/2008. Notifications failing to meet all the acceptance criteria may be treated as informative ones [Pigłowski 2011]. The complete notification must contain information necessary to identify the product concerned (name, brand, model, photos, etc.) and its origin (country, contact details of the marketing authorisation holder), so that it can be distinguished from other similar products [Decyzja wykonawcza Komisji (UE) 2019/417]. In order to ensure that each notification is complete, any missing information required must be explained and compensated for as soon as it becomes available. RAPEX contact points check notifications for correctness and possible duplication [Pigłowski 2018].

According to Appendix I to the GPSD, information on dangerous products is to be provided by companies to competent authorities in the Member States. For this purpose, companies may use the Product Safety Business Alert Gateway tool available on the RAPEX website. The authorities of the Member States are responsible for carrying out risk assessments for dangerous products and notifying the Commission (using the RAPEX application) of mandatory / voluntary measures taken on their territories. Authorities controlling the external borders of the EU follow the same notification procedure as the market surveillance authorities. The European Commission can inform the RAPEX contact points and the Member States about dangerous products (also using tools other than the RAPEX application) based on information obtained from third countries, international organisations, entrepreneurs, other early warning systems, etc. [Muss and Lesiów 2018].

4. METHODS

The study focused on the number and types of notifications of protective masks to RAPEX. The CoViD-19 pandemic forced the widespread use of protective masks, which raises the question whether the available masks met the requirements for PPE. The number of notifications concerning conformity of protective masks in the years 2015-2022 was analysed on the basis of data obtained from RAPEX.

Such notifications, taken from the years 2020–2022, were analysed, taking into account the following criteria:

- reporting country;
- country of origin;
- destination.

A comparison of the number of individual notifications between 2020 and 2022 is also presented.

In order to carry out the research, methods of examining secondary data were used, such as the method of analysis and criticism of literature and the method of examining documents. Therefore, as a combination of the assumptions of these methods, an analysis of existing materials was used.

5. RESULTS

The number of notifications for protective masks placed on the EU market in the following months of 2015–2022 was analysed, based on data from RAPEX (Fig. 1).

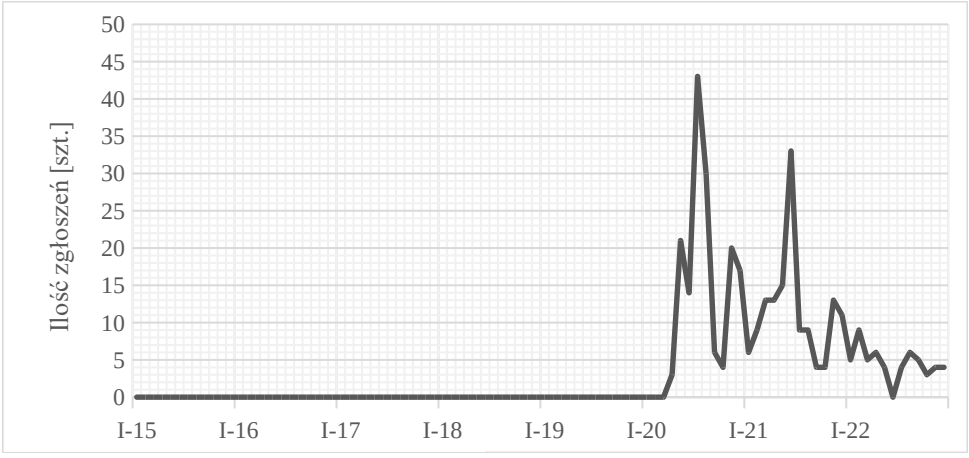

Fig. 1. Notifications for protective masks in 2015–2022 (number)

Source: own study based on information obtained from the RAPEX database – European Commission, 2023, Safety Gate: the EU rapid alert system for dangerous non-food products (20.03.2023), https//ec.europa.eu/safety-gate-alerts/screen/webreport (20.03.2023).

There were no such reports until April 2020. An important fact is that the initial three cases of CoV infection in Europe (France) were confirmed on 24 January 2020 while, three months later on 23 April 2020, the initial three notifications appeared in the RAPEX system in connection with the risk of non-compliance with the requirements set for protective masks.

In the following months, increases and decreases in the number of notifications were visible. However, until the end of 2022, notifications regarding protective masks appeared every month (except June 2022), possibly due to the coercion to cover the mouth and nose, which was tightened or eased depending on the current local pandemic situation. Nevertheless, protective masks were an inseparable element of social life during that period.

A clear increase in the number of notifications to RAPEX was observed in July 2020 and June 2021. The highest number of notifications were recorded in February 2022 but the variability in the number of notifications in the individual months of 2022 was clearly smaller than that observed during the two previous years.

The total number of notifications in the years 2015–2022 is presented in Table 1.

Table 1. Notifications for protective masks in 2015–2022

#	Year(s)	Notifications
1	2015–2019	0
2	2020	158
3	2021	139
4	2022	55

Source: own study based on information obtained from the RAPEX database – European Commission, 2023, Safety Gate: the EU rapid alert system for dangerous non-food products (20.03.2023), https//ec.europa.eu/safety-gate-alerts/screen/webreport (20.03.2023).

158 notifications were recorded on 2020, and only 19 notifications less (139) in 2021. In 2022, however, the number of notifications dropped to 55, possibly due to greater caution on the part of manufacturers, importers and distributors in meeting the requirements for protective masks. The number of notifications received by RAPEX, combined with frequent actions taken by market surveillance authorities including product withdrawals, could act as a warning to those who imported protective masks to the EU as a measure against endangering consumers. The most cases of non-conformity in 2020 and 2021 involved inadequate testing of products and ineffective filtration.

The notifications of protective masks to RAPEX were also examined in terms of the source countries. The number of notifications submitted by individual countries in 2020–2022 is shown in Table 2.

Table 2. Notifications for protective masks by country in 2020–2022

#	Reporting country	Number of notifications			
		2020	2021	2022	Total
1	Germany	9	52	19	80
2	Belgium	60	11	6	77
3	Romania	20	8	0	28
4	Poland	21	3	3	27
5	Italy	5	19	1	25
6	Luxembourg	9	11	2	22
7	Estonia	3	15	1	19
8	Latvia	6	3	1	10
9	Hungary	5	2	3	10
10	Denmark	7	0	0	7
11	Ireland	1	2	4	7
12	Malta	3	3	0	6
13	Iceland	2	4	0	6
14	Slovenia	0	2	4	6
15	Czechia	0	0	5	5
16	Croatia	4	0	0	4
17	Slovakia	0	2	2	4
18	Spain	2	0	0	2
19	France	0	0	2	2
20	UK	1	0	0	1
21	Lithuania	0	1	0	1
22	The Netherlands	0	1	0	1
23	Finland	0	0	1	1
24	Norway	0	0	1	1
Total		**158**	**139**	**55**	**352**

Source: own study based on information obtained from the RAPEX database – European Commission, 2023, Safety Gate: the EU rapid alert system for dangerous non-food products (20.03.2023), https//ec.europa.eu/safety-gate-alerts/screen/webreport (24.03.2023).

In 2020, the country with the most notifications (60) was Belgium, followed by Poland (21) and Romania (20). Other countries submitted up to 9 notifications. It can therefore be assumed that the market surveillance authorities acted most efficiently in Belgium. Next, in 2021, the most notifications came from Germany (52), which

was followed by Italy (19) and Estonia (15). Belgium and Luxembourg reported the alert 11 times, and the remaining countries from up to 8 times (Poland 3 times).

In 2022 there was a significant drop in the number of notifications from individual countries, which suggests that the market stabilised due to the abatement of the pandemic, but also a possible relaxation of vigilance of market surveillance authorities. as in the previous year, the only country to stand out, was Germany (19 notifications, 35% share). Germany and Belgium submitted the most notifications in 2020–2022 (45% of all), from which it can be concluded that market surveillance authorities operated most efficiently in these countries.

RAPEX contains important data on the number of notifications depending on the country of origin of protective masks (Tab. 3).

Table 3. Notifications by country of origin of protective masks in 2020–2022

#	Country of origin	Number of notifications			
		2020	2021	2022	Total
1	China	139	112	29	280
2	Unknown	10	9	5	24
3	Turkey	2	10	11	23
4	Germany	0	3	0	3
5	Czechia	0	1	2	3
6	Mexico	2	0	0	2
7	Vietnam	1	1	0	2
8	Egypt	0	1	1	2
9	Hong Kong	0	1	1	2
10	France	0	0	2	2
11	Denmark	1	0	0	1
12	Spain	1	0	0	1
13	Ukraine	1	0	0	1
14	UK	1	0	0	1
15	Portugal	0	1	0	1
16	Lithuania	0	0	1	1
17	Poland	0	0	1	1
18	S. Korea	0	0	1	1
19	Tunisia	0	0	1	1
Total		**158**	**139**	**55**	**352**

Source: own study based on information obtained from the RAPEX database – European Commission, 2023, Safety Gate: the EU rapid alert system for dangerous non-food products (20.03.2023), https//ec.europa.eu/safety-gate-alerts/screen/webreport (25.03.2023).

In 2020, 139 notifications concerned protective masks produced by Chinese factories. The country of origin of the masks was not specified in 10 notifications. There were also 2 notifications of protective masks from Mexico and Turkey. By contrast, protective masks from Denmark, Spain, Ukraine, the UK and Vietnam were reported only once. A clear prevalence in the number of notifications concerning masks of Chinese origin was observed, accounting for 94% of all notifications (excluding notifications concerning protective masks of unknown origin).

In 2021, 112 notifications (86%) concerned protective masks made in China. Only 10 notifications concerned protective masks from Turkey, while in 9 cases the country of origin was not known. In 2021, there were 8% fewer reports for China than in 2020, possibly due to the fact that the prolonged pandemic caused an increase in the production of protective masks in Europe. In response to the pandemic situation, many companies decided to extend their business on the production of PPE as the demand for protective masks did not decrease in 2020.

In 2022, protective masks from China notified to RAPEX accounted for a slightly smaller, but still high, percentage (58%, 29 notifications). Given the substantial decrease in the overall number of notifications, it can be assumed that many non-conforming masks did appear on the market but were not detected, or the situation related to the fulfillment of the requirements by manufacturers normalised. Despite that, notifications for protective masks originating in China still accounted for 85% of the total number between 2020 and 2022 (Fig. 2).

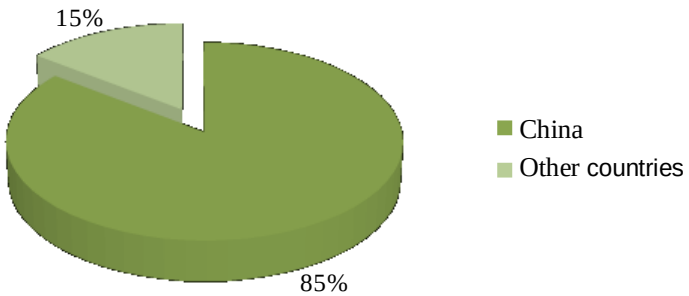

Fig. 2. Percentage shares of notifications for protective masks originating in China (dark green) vs. other countries (light green) in 2020–2022

Source: own study based on information obtained from the RAPEX database – European Commission, 2023, Safety Gate: the EU rapid alert system for dangerous non-food products (20.03.2023), https//ec.europa.eu/safety-gate-alerts/screen/webreport (25.03.2023).

China is the country from which the CoViD-19 epidemic began. Thus, the Chinese were the first who had to take up the fight against the spreading virus. The situation forced them to stock up on all kinds of PPE to help contain the rise in infections, but it also left a significant scope for abuse. Fraudsters who manufactured

non-conforming products hoped that they would not be inspected. However, bearing in mind the interest of consumers, the task of the RAPEX system is to warn them about dishonest manufacturers and withdrawn products. It is worrying that so many protective masks from China did not meet the EU's requirements. Enforcement measures were applied to dishonest companies, such as a ban on placing products on the market, withdrawal from the market, withdrawal from the end user, or labeling with warnings. This will be the subject of further research.

An analysis of the number of notifications for protective masks in 2020–2022 in terms of their intended use shows that, in 2020, 157 notifications concerned masks for consumer use, while only one involved a product for professional use. In 2021, only 6 out of 139 notifications concerned products for professional use, and in 2022 no such mask was reported. Based on this data for the 2020–2022 period, masks for consumer use accounted for 98% of all the reported masks.

6. CONCLUSIONS

At the beginning of the analysis of data from the RAPEX database, questions were asked about the impact of the CoViD-19 pandemic on the number of notifications regarding protective masks, countries that submitted the most notifications, and the country that delivered the largest number of non-conforming protective masks in 2020–2022.

The question about the impact of the CoViD-19 pandemic on the number of notifications to RAPEX was answered in the affirmative. It has been confirmed that 3 months after the detection of the initial cases of CoV infection in the European Union were identified, reports of non-conformity of protective masks appeared in the RAPEX system, for the first time since 2015. Like all other products that must meet certain requirements for the placement on the European market, protective masks were inspected many times by market surveillance authorities. The exchange of information on dangerous non-food products within the Community resulted in non-conformity reports appearing in RAPEX. The absence of notifications in the initial five years studied, the sudden increase in 2020, the stabilisation in 2021 and the decrease in 2022 clearly indicate that the CoViD-19 pandemic had a significant impact on the number of notifications for protective masks.

The question about the country that submitted the most notifications in the years 2020-2022 has also been answered: the countries that acted most efficiently during this period and sent the most notifications of non-nonconformity were Germany and Belgium.

Finally, the answer to the question about the country of origin of the largest number of protective masks reported to the RAPEX system in the years 2020–2022 is: China. In total, 85% of masks reported as non-conforming between 2020 and 2022 were of Chinese origin.

An analysis of notifications to RAPEX concerning protective masks illustrates the impact of the pandemic on compliance of these products with the European requirements. Unfortunately, the large number of non-conforming products gives rise to a suspicion that their manufacturers deliberately neglected the know-how necessary to place safe products on the European market. This poses a significant risk for consumers who are not aware of unsuitability of products they purchase. The consumer wrongly believes that non-conforming products will be stopped from entering the market or, if this has already happened, the product will be recalled. This risk can be avoided by carrying out reliable conformity assessments based on the relevant European requirements and, if necessary, by turning to competent bodies for help.

The study on notifications of protective masks to RAPEX reveals the existence of problems related to safety of these products on the European market. On the other hand, the study has its limitations, mostly due to the heterogeneity of notifications. Notifications to RAPEX differ in terms of data quality and detail of information, which will be of particular importance in further studies on RAPEX notifications concerning protective masks with regard to the causes of non-conformity and types of risks as well as measures taken against reported manufacturers, importers and/or distributors.

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