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Evaluation of Protective Mask Notifications to the Safety Gate/RAPEX System during the COVID-19 Pandemic

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ABSTRACT

Objective: This study aims to assess the protective mask notifications used in the Safety Gate/RAPEX system (an early warning system for managing safety used by the European Commission) between 2020 and 2022 in the context of the COVID-19 pandemic. This study continues research into the impact of the COVID-19 pandemic on the notification of protective masks for this system.

Research Design & Methods: Legacy data analysis combines literature evaluation and critique with document research method.

Findings: Notifications on protective masks offered between 2020 and 2022 were analysed taking into account four factors: the types of legal provisions that were not met, the non-compliances uncovered, and the categories of voluntary and required measures applied. In 2020, 41% of notifications failed to refer to a specific standard pertaining to the regulation on personal protective equipment. In contrast, during the two subsequent years, we can observe a systematic decrease in the lack of standard indication. Between 2020 and 2022, the reasons for notifications

against protective masks that occurred most frequently included ineffective filtration and the lack of adequate testing of the product by a competent body. Voluntary and required measures taken by economic entities against non-compliant protective masks that may pose risks to consumers have been characterised.

Implications/Recommendations: The COVID-19 pandemic affected the completeness of notifications for protective masks in the Safety Gate/RAPEX system and the availability of protective masks that were not tested and had ineffective filtration, to consumers. Voluntary and required measures mostly included product withdrawals from the market and from end users. It is recommended that Member State regulatory authorities improve the quality of the notifications provided.

Contribution: Notifications on protective masks are characterised in the Safety Gate/Rapex system in the context of the COVID-19 pandemic. The need for continuous improvement of the effectiveness of European market surveillance and the dangerous products early warning system was identified.

Article type: original article.

Keywords: protective masks, Safety Gate/RAPEX system, COVID-19 pandemic, dangerous products.

JEL Classification: D18, F15, K32.

1. Introduction

The European Commission (EC) has an early warning system for managing safety, called Safety Gate/RAPEX. The database used by this system provides information on dangerous non-food products sold on the EU markets (Neza & Centini, 2016). These include personal protective equipment (PPE) that do not comply with EU requirements, including protective masks (filtering half masks). The availability and protection effectiveness of masks took on unprecedented importance during the COVID-19 pandemic. The dictum to cover one's mouth and nose in public spaces was introduced as a main preventive measure to limit the spread of the SARS-CoV-2 virus (Krzyżak *et al*., 2020). In order to address the shortage of PPE, an essential task during the pandemic, the European Commission issued recommendations which allowed for the introduction of PPE on the EU market without CE marking, for a limited period of time, provided that they were recognised by the relevant market surveillance authorities as compliant with essential health and safety requirements (Commission Recommendation (EU) 2020/403).

The Safety Gate/RAPEX system is key to protecting consumers from hazardous products. Protective masks, as products directly related to public health, require special compliance with standards and regulations. Analysis of the protective masks notifications in the Safety Gate/RAPEX system could provide important

information on changes in the quality and compliance of products launched during the COVID-19 pandemic. During that period there was a surge in demand for protective masks, leading to an increased number of Safety Gate/RAPEX notifications (European Commission, 2021). This is supported by the results of a study by Wierzowiecka and Dąbrowska (2023), which identified a lack of notifications in the first five years examined and a high level of notifications observed in 2020 (158 notifications), followed by a similar number in 2021 (139 notifications) and a decrease in 2022 (55 notifications).

This shows that the COVID-19 pandemic increased the number of protective mask notifications to the Safety Gate/RAPEX system. 98% of all notified protective masks were ones intended for consumer use. From 2020 to 2022, the countries with the highest number of protective mask notifications (45%) included Germany and Belgium, suggesting that these countries had the most operationally efficient market surveillance authorities. Data in the Safety Gate/RAPEX system concerns the number of protective mask notifications in terms of their origin. It was found that, during the study period, 85% of notifications of non-compliant protective masks originated from China (Wierzowiecka & Dąbrowska, 2023). The preponderance of products originating in China in the early warning system has been confirmed by other studies (Pigłowski, 2018a; Purves & Echikson, 2021).

The COVID-19 pandemic had a huge impact on both society and the economy (Mohajan, 2020; Clemente-Suárez *et al*., 2021; Naseer *et al*., 2023). The pandemic led to rapid and frequent changes in the PPE regulations (Goniewicz *et al*., 2020). The rapid introduction of new products to the market may have affected the quality of the testing and certification processes that are indispensable to the CE marking being affixed to protective masks as required. Understanding how the law and standards were applied in practice *vis-à-vis* the Safety Gate/RAPEX notifications concerning protective masks can provide valuable information for future emergencies. In addition, knowledge of the most common actions taken by operators in response to notifications can improve our understanding of how effectively the Safety Gate/RAPEX system protects consumers from unsafe products. It can also help companies better prepare for potential risks as well as avoid recurring problems.

The COVID-19 pandemic may have led to errors or inaccuracies in the Safety Gate/RAPEX notifications, with serious implications for public safety. Research findings on the quality of notifications of various products to the Safety Gate/RAPEX system confirm that the system has gaps and incomplete information (Purves & Echikson, 2021). At the same time, other studies based on the Safety Gate/RAPEX system database fail to provide complete data on the protective mask notifications in this system, especially between 2020 and 2022. Findings from those studies extended to the relationships between the category of notified prod-

ucts and other data including country of origin, level of risk and measures adopted (Muss & Lesiów, 2018; Pigłowski 2018a, 2023). Still other studies have focused on identifying the main risks for consumers, including injury, poisoning, allergic reactions, and choking and suffocation, with the risks varying significantly with the product groups (Hernik, 2022). Studies have also been done on particular product categories reported in the Safety Gate/RAPEX system, such as personal care products (Klaschka, 2017), microbiologically contaminated cosmetics and cosmetic products with too many preservatives (Neza & Centini, 2016), and passenger cars (Pigłowski, 2018b).

For its part, research on protective masks primarily evaluates them for their mechanical, physicochemical and performance properties, including wettability, absorbency and stretch (Mędrowska & Łagan, 2021), filtration efficiency (Mueller *et al*., 2018; Konda *et al*., 2020; Wang *et al*., 2023), total internal leakage (Steinle *et al*., 2018), or analysis of individual respiratory protection by protection classes and contaminant type (Harmata & Kamionek, 2021). Research findings, including a review of standards and test methods for protective masks, have been identified (Forouzandeh, O'Dowd & Pillai, 2021). Pecchia *et al*. (2020) conducted research on regulatory frameworks for the personal protective equipment during crises. Work has also been done on commercially available anti-smog filtering half masks with and without CE marking and their compliance with the requirements of the harmonised standard EN 149:2001 + A1:2009 (Brochocka, Pośniak & Skowroń, 2018). Others have addressed the differences between CE-certified and non-CE--certified masks (Damiani *et al*., 2021).

In addition, in the context of the COVID-19 pandemic, research has been conducted on the requirements and orders to wear protective masks (Badora-Musiał, 2020), the ethical aspects of state-level decisions on the wearing of protective masks (McDonald *et al*., 2020), and public attitudes towards the dictum to cover one's nose and mouth (Krzyżak *et al*., 2020).

Few detailed scientific studies have been done that directly analyse the impact of the COVID-19 pandemic on the Safety Gate/RAPEX protective mask notifications in the context of proper identification of unfulfilled legal provisions, reasons for notifications (such as lack of tests, lack of CE marking), or specific voluntary and required measures taken by economic operators in response to notifications. There remains a need for detailed analyses and consideration of the specific circumstances of the COVID-19 pandemic period. Such studies are crucial for public health and the quality of protective products during a health crisis. Accordingly, this paper seeks an answer to the following questions:

1. Did the COVID-19 pandemic affect the proper identification of legislation and standards in the protective mask notifications to the Safety Gate/RAPEX system between 2020 and 2022?

2. Was the lack of CE marking the most common reason that the Safety Gate/RAPEX system received notifications on protective masks between 2020 and 2022?

3. Did the COVID-19 pandemic affect the performance of required testing of the protective masks the Safety Gate/RAPEX system was notified about between 2020 and 2022?

4. What were the most common voluntary and required measures taken by economic entities as a result of the Safety Gate/RAPEX notifications between 2020 and 2022?

Again, this research assesses the protective mask notifications to the Safety Gate/RAPEX system between 2020 and 2022 in the context of the COVID-19 pandemic. Research methods included the secondary data research (literature evaluation, critique, and document research). The legacy data in the Safety Gate/RAPEX system was the main subject of research.

2. The European Rapid Alert System for Dangerous Products – Safety Gate/RAPEX

The Safety Gate/RAPEX system (Rapid Alert System for dangerous non-food products) is a notification system intended for the rapid exchange of information between the national authorities of countries within the European Economic Area (the 27 Member States of the European Union and Iceland, Liechtenstein and Norway) and the European Commission on measures taken with regard to dangerous products on the market in the European Economic Area. The exchange of information refers to measures and actions taken on dangerous consumer and professional products (excluding food, feed, pharmaceuticals and medical devices) to prevent and reduce the risks for consumers. The Safety Gate/RAPEX system comprises two types of notifications: notifications and notifications for information. This notification system aims to prevent dangerous products from being delivered to consumers and to take corrective measures, such as the withdrawal or recall of such products from the market (Commission Implementing Decision (EU) 2019/417).

The RAPEX system was established under Article 12 of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (GPSD). The guidelines for managing the EU Rapid Information System RAPEX and the related notification system were governed by Commission Implementing Decision (EU) 2019/417 of 8 November 2018. These guidelines establish notification mechanisms and related processes, the types of data to be entered, the deadlines for different actions, and define and categorise voluntary and required measures taken by economic entities who introduced dangerous products to the market (Commission Implementing Decision (EU) 2019/417). Voluntary measures are implemented voluntarily by the product-responsible entity, while required

measures are taken as a result of an order from Member State authorities (Vincze, Al Dahouk & Dieckmann, 2019).

In order to enable more effective corrective measures to be taken for products that present a risk on the European market, the RAPEX system was upgraded under EU Regulation 2023/988 on General Product Safety (GPSR). It entered into force on 12 June 2023 and became applicable on 13 December 2024, replacing the General Product Safety Directive (GPSD) 2001/95/EC. In order to provide better clarity and reach consumers more effectively, the abbreviated name has been changed from RAPEX to Safety Gate. Under this regulation, Safety Gate comprises three elements:

– Safety Gate rapid alert system – an early warning system for non-food dangerous products allowing national authorities and the European Commission to exchange information on such products,

– Safety Gate portal – an Internet portal for informing the public and enabling members of the public to lodge complaints,

– Safety Business Gateway portal – an Internet portal enabling businesses to fulfil their obligation to inform authorities and consumers about dangerous products and accidents (EU Regulation 2023/988).

3. Characteristics of the EU Legal Requirements for Protective Masks

Protective masks (filtering half masks) are face masks designed to protect against particles such as solid and liquid aerosols. They are subject to various legal standards around the world. These standards specify certain necessary physical properties and performance characteristics for half masks to comply with a given standard (3M, 2021).

In the European market, filtering half-masks belong to the category "personal protective equipment," which are products manufactured to protect the health and safety of their users. Such products must comply with the Community harmonisation legislation, which provides for their CE marking in accordance with Regulation (EC) No 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.

The essential requirements for all PPE, as concerns their being made available on the EU market, are set out in Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment (PPER). These requirements apply to design principles, harmlessness, comfort and effectiveness, lightness and durability, while taking into account the category of PPE and the risks identified (Regulation (EU) 2016/425). Personal protective equipment intended to protect the respiratory system should allow one to breathe air in a contaminated

atmosphere. This air must be obtained under a suitable method, here the filtration. The filtration capacity, as well as the tightness of the facepiece, must ensure an adequate level of safety for the user. The materials used for a particular equipment must guarantee proper breathing and adequate hygiene. If the equipment includes filters, the instructions must include information on the maximum storage time for a new filter in its original packaging (Regulation (EU) 2016/425; Brochocka, Pośniak & Skowroń, 2018).

The standard applicable to filtering half masks and harmonised with Regulation 2016/425 is: EN 149:2001 + A1:2009 Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking.

Filtering half masks are classified according to their filtration efficiency and total internal leakage, i.e. (Majchrzycka, Pośniak & Górny, 2020):

– FFP1 (P1 – aerosol particle penetration of 20%),
– FFP2 (P2 – aerosol particle penetration of 6%),
– FFP3 (P3 – aerosol particle penetration of 1%).

This means that the subsequent numerical values indicate the increasing filtering efficiency of potentially harmful particles in the air. Depending on the type, FFP1, FFP2 and FFP3 masks are impermeable to respectively: 80%, 94% or 99% of harmful aerosol particles 300 nm and above (Badora-Musiał, 2020).

The Safety Gate/RAPEX system does not include medical masks within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR). By covering the mouth and nose, medical masks provide a barrier to minimise the direct transmission of infectious agents between staff and patients and do not constitute personal protective equipment (CIOP, 2021). While their primary purpose is to protect the patient, in certain circumstances they may also protect the user from the splashing of potentially contaminated fluids. Medical masks should comply with the requirements of harmonised standard EN 14683 + AC:2019 Medical face masks – Requirements and test methods (Rubio-Romero *et al*., 2020).

4. Materials and Research Methods

This study analysed the protective mask notifications to the EU Early Warning and Information Exchange System for non-food dangerous products (Safety Gate/RAPEX) during the COVID-19 pandemic (2020–2022). Given the results of the previous research (Wierzowiecka & Dąbrowska, 2023), which indicated a high number of Safety Gate/RAPEX notifications for protective masks during these years and the fact that the majority of non-compliant consumer protective masks originated from China, questions were raised regarding the legal provisions that went unsatisfied, the reasons for the notifications and the preventive measures applied to economic entities. Data from the Safety Gate/RAPEX system were

used to analyse the protective mask notifications between 2020 and 2022. They considered:

– the reason for notifications by type of legislation,
– the types of non-compliance identified,
– the categories of voluntary measures taken by economic entities,
– the categories of required measures applied to economic entities.

The numerical material indicating notifications related to the above factors underwent statistical analysis, using Statistica 13.3, with a chi-square independence test (Stanisz, 2006). The test was applied to verify the hypotheses on the dependence of the frequency of factors differentiating the notifications on the year of the survey. Calculations were not performed for those causes for which – according to the test conditions – there were at least two empirical counts lower than 5. The verification was performed at the significance level $\alpha = 0.05$, based on the test probability value *p*. The test results are presented in Tables 3–6.

Secondary data research methods (literature evaluation, critique, document research) were used alongside the legacy data analysis.

The article is based on the analysis of the EU legislation on product safety and the Safety Gate/RAPEX system, as well as the requirements for personal protective equipment, including protective masks. Other research results on the Safety Gate/RAPEX system and protective masks were analysed.

As the Safety Gate/RAPEX system which produced the data only allows notifications to be filtered according to basic parameters, such as product categories or notifying country, in order to obtain the data indispensable for the analysis, every mask notification during the period under consideration was reviewed.

5. Results

A study done by Wierzowiecka and Dąbrowska (2023) analysed the number of Safety Gate/RAPEX notifications on protective masks launched on the EU market between 2015 and 2022 (Table 1).

Table 1. Number of Safety Gate/RAPEX Notifications of Protective Masks between 2015 and 2022

Years	2015–2019	2020	2021	2022
Number of notifications	0	158	139	55

Source: the authors, based on the Safety Gate/RAPEX database (European Commission, 2023).

As a follow-up to the study, by using the data from the Safety Gate/RAPEX system, notifications of protective masks between 2020 and 2022 were analysed through the lens of the legal provisions they transgressed (Table 2).

Table 2. Percentage of Safety Gate/RAPEX Notifications on Protective Masks by the Legal Provisions That Constituted Grounds for Notifications between 2020 and 2022

Legal Provision as Grounds for Notification	Percentage		
	2020	2021	2022
Non-compliance with PPER (Personal Protective Equipment Regulation)	97	98	93
Non-compliance with MDR (Medical Devices Regulation)	2	0	0
Non-compliance with GPSD (General Product Safety Directive)	0	1	2
Non-compliance with GPSD (General Product Safety Directive) and BPR (Biocidal Products Regulation)	0	1	0
No indication	1	0	5

Source: the authors, based on the Safety Gate/RAPEX database (European Commission, 2023).

In 2020, 97% of notifications were for non-compliance with the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment (PPER). Non-compliance with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) was indicated as the reason for 2% of notifications, while no legal provision was indicated in 1% of notifications. In contrast, in 2021, failure to comply with the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council (PPER) was cited as the reason for the majority of notifications (98%). Only 1% of the remaining notifications included non-compliance with the requirements of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (GPSD). One notification also covered non-compliance with the requirements of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR). This notification related to the presence of polyhexanide in the mask fabric. The reasons for the 2022 notifications followed a similar pattern, with 93% related to the PPER regulation, 2% including non-compliance with the GPSD and 5% failing to indicate a legal provision for the notification.

The reason for non-compliance with the requirements of the PPER most frequently involved the non-compliance of protective masks with the requirements of EN 149:2001 + A1:2009 Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking. A breakdown of the percentage of non-compliance with EN 149 as a reason for non-compliance with the requirements of PPER between 2020 and 2022 and the results of analysis with the use of chi^2 test are presented in Table 3.

Table 3. Percentage of the Safety Gate/RAPEX Notifications of Protective Masks in Relation to the Reasons for Non-compliance with the Requirements of the Personal Protective Equipment Regulation between 2020 and 2022

Reason for Notification	Percentage			Chi^2	*p*
	2020	2021	2022		
Non-compliance with EN 149 standard	59	88	91	29.57	< 0.001
No indication of PPER particular standard	41	12	9	33.41	< 0.001

Source: the authors, based on the Safety Gate/RAPEX database (European Commission, 2023).

The *p* values allow us to reject both hypotheses – that the frequency of reporting non-compliance with EN 149 standard and the frequency of no indication of the correct standard – is independent of the particular years of the pandemic. In 2020, as much as 41% of the notifications failed to indicate a specific standard referring to the PPER regulation. In the two subsequent years, a steady decrease in the lack of indications of EN 149 standard can be observed (12% in 2021 and 9% in 2022). This indicates that notifications were incomplete in the first year of the pandemic.

This was followed by an examination of the number of the Safety Gate/RAPEX notifications between 2020 and 2022 related to protective masks with regard to the reasons for non-compliance. Table 4 presents the results on the reasons for non--compliance indicated in the notifications, in percentage terms, and the results of analysis with the use of chi^2 test.

Table 4. Percentage of the Safety Gate/RAPEX Notifications of Protective Masks and the Reasons for Non-compliance between 2020 and 2022

Reasons for Non-compliance	Percentage			Chi^2	*p*
	2020	2021	2022		
The product has not been adequately tested	39	27	8	25.48	< 0.001
Ineffective filtration	37	58	85	46.02	< 0.001
Inadequate facial fit	18	10	3	22.42	< 0.001
Inadequate mask design	6	4	2	–	–
Incomplete documentation and/or wrong directions for use	0	1	2	–	–

Source: the authors, based on the Safety Gate/RAPEX database (European Commission, 2023).

The *p* values allow us to reject all hypotheses of the frequency of reasons for non-compliance (inadequate testing, ineffective filtration and inadequate facial fit) being independent of the year of testing. The frequency of the lack of testing clearly decreased in the subsequent years of the pandemic, which may be indicative of a hasty introduction of protective masks into the market, without adequate research

into the high demand for these products on the market. On the other hand, with the subsequent years of the pandemic, the number of notifications indicating ineffective filtration as the reason for non-compliance clearly rose. This may be because the supervision of testing became better organised as the pandemic progressed, revealing that protective masks were ineffective in terms of filtration.

In 2020, the most frequently occurring reason for non-compliance (39%) was the lack of adequate testing of the product by a competent authority. A slightly smaller number of notifications (37%) identified that the product featured ineffective filtration. 18% of notifications were for improper facial fit, which could lead to an ineffective use of the mask. A year later, in 2021, the most frequently occurring reason for non-compliance (58%) was ineffective filtration. 27% of notifications were for improperly tested product, 10% for improper facial fit and 4% for improper mask manufacture. In 2022, as many as 85% of notifications were for ineffective filtration, while only 3% of notifications were for product not being properly tested. Other reasons were reported occasionally. Note that more than one reason for non-compliance could be given in a notification, and in many cases the product failed to meet the technical requirements for multiple reasons. When non-compliance is identified, economic entities are obliged to take preventive and restrictive measures. Table 5 presents voluntary measures (those taken without the intervention of the Member State authorities) implemented for the protective masks that were reported. It includes the results of analysis under chi^2 test.

Table 5. Percentage of Notifications Including the Application of a Particular Voluntary Measure by Economic Entities between 2020 and 2022

Category of Voluntary Measure		Percentage						Chi^2	*p*
		2020		2021		2022			
Withdrawal of product from the market (including the online market)		48		43		22		18.26	0.003
Withdrawal of product from end users		24		34		36		15.96	0.012
No marketing authorisation granted	suspension of sale	7	24	11	16	18	20	3.21	0.126
	import rejected at border	10		1		0			
	marketing ban	7		3		2			
Destruction of product		4		4		10		–	–
Marking of product with appropriate warnings		0		2		8		–	–
Attachment of required documents		0		1		2		–	–
Taking actions to remove the product defect		0		1		2		–	–

Source: the authors, based on the Safety Gate/RAPEX database (European Commission, 2023).

In 2020 and 2021, the economic entities opted most often for product recall (48% in 2020 and 43% in 2021). In 2022, this voluntary measure was also taken in numerous, though fewer, cases (22%). Recalling product from end users was another common voluntary measure – 24%, 34% and 36% in the three years, respectively.

The *p* values allow us to reject the two hypotheses on the frequency of the distinguished categories (recall and end-user recall) being independent of the different years of the pandemic. The values in Table 5 indicate that a decrease in the percentage value was observed for the first case, especially in 2022, while there was an increase in the percentage value in the second case, especially after 2020.

For the purpose of testing, a common category of voluntary measures was formed. It concerned actions intended to prevent non-compliant protective masks from entering the market (withholding of sales, rejection of imports at the border, prohibition of marketing). The value $p = 0.126$ does not allow us to reject the hypothesis that the frequency of no marketing authorisations granted is independent of the year of testing. The percentage of this measure remained at a similar level.

In contrast, required measures (those forcing the economic entity to implement preventive, corrective or restrictive actions for products posing risks) are imposed by Member State authorities. Table 6 presents the percentage of notifications including the application of a particular required measure by economic entities between 2020 and 2022 and the results of analysis under chi^2 test.

Table 6. Percentage of Notifications That Included the Application of a Given Required Measure by Economic Entities between 2020 and 2022

Category of Required Measure		Percentage						Chi^2	*p*
		2020		2021		2022			
Withdrawal of product from the market (including the online market)		15		43		44		18.24	0.001
Withdrawal of product from end users		7		34		17		10.96	0.002
No marketing authorisation granted	suspension of sale	0	46	11	16	7	33	12.25	0.002
	import rejected at border	20		1		3			
	marketing ban	26		3		23			
Destruction of product		1		4		0		–	–
Marking of product with appropriate warnings		30		2		3		–	–
Attachment of required documents		0		1		0		–	–
Taking actions to remove the product defect		0		1		0		–	–
Actions taken to remove the product defect		1		0		3		–	–

Source: the authors, based on the Safety Gate/RAPEX database (European Commission, 2023).

It was found that in 2020, for 30% of notifications, Member State authorities ordered that the product be marked with appropriate warnings. In contrast, 26% of notifications referred to a ban on launching the protective masks on the market and 20% to a rejection of imports at the border. The product recall referred only to 15% of notifications. In contrast, in 2021 and 2022, such a required measure was applied most frequently (43%). In addition, in 2021, entities were frequently ordered to withdraw the protective masks from end users (34%) and to halt sales (12%). Required measures that were also frequently applied in 2022 included marketing bans (23%) and product recall from end users (17%).

As in the case of voluntary measures, for the purpose of testing, a common category of required measures was created for efforts aimed at preventing non-compliant protective masks from entering the market. The *p* values allowed for the rejection of all hypotheses on the frequency of the distinguished categories being independent of the particular years of the pandemic. The values in Table 6 show that there was a threefold increase in recall frequency after 2020, while an increase in end user recall frequency was observed after 2020 and a decrease in 2022. There was a nearly threefold decrease after 2020 in actions aimed at granting no marketing authorisation and a twofold increase after 2021.

6. Discussion

Upon undertaking the analysis of the data from the Safety Gate/RAPEX system database, questions were raised regarding the notifications of protective masks relative to the reasons for notifications by type of legislation, non-compliance identified, and measures taken against notified economic entities.

In terms of the correct indication of legal provisions and standards in the notifications of protective masks in the Safety Gate/RAPEX system between 2020 and 2022, it was found that an overwhelming majority (more than 90% each year during the period examined) of non-compliance with the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment (PPER) was correctly indicated. In 2020, on the other hand, only 2% of notifications concerned non-compliance with the requirements governing Medical Devices Regulation (MDR) and were specified in detail as non-compliance with the requirements of EN 14683 Medical face masks – Requirements and test methods. The Safety Gate/RAPEX system fails to cover medical devices falling within the scope of Regulation (EU) 2017/745, but in this case the products notified were *de facto* not certified as medical devices by an authorised notified body. The information on the packaging was misleading to the consumer by suggesting that the product met the requirements of the aforementioned MDR. Furthermore, these notifications were made as information notifications.

In 2020, when the COVID-19 pandemic began, many notifications (41%) failed to indicate a specific standard referring to the PPER regulation. In the two subsequent years, the lack of indications of a standard had decreased (12% and 9%), demonstrating that the situation eventually stabilised and that the notifying entities became more knowledgeable. The results indicate that the COVID-19 pandemic had an impact on the completeness of protective mask notifications, particularly with regard to indications of non-compliance with the relevant harmonised standard. This is confirmed by the results of a study conducted in the first half of 2020 and published by European Centre for International Political Economy on the quality of the Safety Gate/RAPEX notifications, which found that many notifications contained basic product information at best. This became apparent at the start of the COVID-19 pandemic with regard to pandemic-related products including masks and disinfectants (Purves & Echikson, 2021). Admittedly, the European Commission requests additional details from national authorities before approving the alerts if insufficient data is provided. However, the European Commission is legally obliged to publish the available information in the Safety Gate/RAPEX system as early as possible, with the assumption that it can be updated later, which is not always the case (Purves & Echikson, 2021). The results of research (Pecchia *et al*., 2020) indicate that the European Union's regulatory framework regarding the PPE certification for a crisis situation such as the COVID-19 pandemic is inadequate.

The lack of CE marking was not the most common reason that the Safety Gate/RAPEX system received notifications on protective masks between 2020 and 2022. Between 2020 and 2022, the most frequently reported reasons for notification were in fact ineffective filtration and a lack of adequate product testing by a competent authority. Products notified had CE marking, but it was not supported by relevant tests confirming compliance with the requirements and at the same time constituting grounds for CE marking. By issuing a declaration of conformity and marking their product with the CE marking, manufacturers were certifying that their product complied with requirements, which was in fact not true. Research has confirmed that protective masks without CE marking failed to meet the protective and performance requirements of EN 149 (Brochocka, Pośniak & Skowroń, 2018) and caused side effects in patients who used them (Damiani *et al*., 2021).

In answer to the question on the impact of the COVID-19 pandemic on the lack of testing of protective masks notified to the Safety Gate/RAPEX system between 2020 and 2022, it was found that in 2020, the reason for notifying authorities about non-compliant protective masks, which occurred most frequently (39%), was that adequate testing was not performed by a competent authority. In 2021, inadequate testing was the second most common reason for notifications (27%), while in 2022 the figure fell precipitously, to 3%, i.e. after decreasing the risk resulting from the COVID-19 pandemic. It can therefore be concluded that the COVID-19 pandemic

led to the required testing of protective masks about which the Safety Gate/RAPEX system was notified between 2020 and 2022. The relevance and types of testing required for protective masks to be effective in the context of the COVID-19 pandemic is highlighted by Forouzandeh, O'Dowd and Pillai (2021). In contrast, Pecchia *et al*. (2020) found that standards for protective masks that can be maintained under normal conditions become untenable in EU Member States during crises.

We can observe that, during the period under study, filtration coming in below the manufacturer's guaranteed values was the main reason for notifications. Insufficient particle retention in the material and/or total filtration capacity were the main causes of the sub-par performance. These two reasons were cited in more than half of the notifications (35% in 2020, 58% in 2021, 85% in 2022). Inspections showed that protective masks failed to provide manufacturers' guaranteed filtration performance. Were additional protective measures not applied, an excessive volume of particles or micro-organisms could pass through the masks, increasing the risk of infection. Indeed, Wang *et al*. (2023) highlighted the urgent need for improved standards of filtration efficiency as well as the fit of protective masks to improve their overall protective efficiency against COVID-19.

The fourth question – What were the most common voluntary and required measures taken by economic entities as a result of the Safety Gate/RAPEX notifications between 2020 and 2022? – proved possible to answer. In 2020, numerous required measures were taken. These included orders to mark product with appropriate warnings (30%), bans on placing the product on the market (26%) and the halting and rejection of imports at the border (20%). These figures are supported by the results of the Safety Gate/RAPEX notification survey from January to August 2020, which found that not all dangerous products listed in the Safety Gate/RAPEX system were recalled. Some were simply banned from import, while others had a risk warning printed on them (Purves & Echikson, 2021). This may be indicative of Member States' non-standard approach during the COVID-19 pandemic towards protective masks the Safety Gate/Rapex system received notice on. In the two subsequent years, the most frequently cited required measure was product recall (including in online markets). Considering the entire period under study, measures involving protective mask recalls and recalls from end users accounted for more than half of the required actions taken.

Voluntary measures taken on the initiative of the economic entity which launched the product or distributed it on the market with regard to protective masks presenting some risk mostly involved product recalls and/or recalls from end users (in total 72% in 2020, 77% in 2021, 58% in 2022). This may indicate that economic entities were responsible, at least those acting in the absence of intervention from a Member State authority or under agreements concluded with these authorities.

The survey involved some limitations mainly related to the heterogeneity and incompleteness of notifications, as specified above. Notifications should contain as complete information as possible. Where required information is not available at the time of notification, the notifying Member State shall clearly indicate it in the form, together with an explanation to that effect (Commission Implementing Decision (EU) 2019/417).

7. Conclusions

The results obtained allow for the following conclusions:

1. The COVID-19 pandemic had an impact on the completeness of protective mask notifications to the Safety Gate/RAPEX system, particularly with regard to the lack of indication of a harmonised standard that was not satisfied.

2. The COVID-19 pandemic had an impact on the availability, to consumers, of protective masks that had not been tested.

3. Ineffective filtration was the most common reason that Safety Gate/RAPEX notifications of protective masks were made between 2020 and 2022.

4. Voluntary measures taken by economic entities and required measures taken against economic entities which launched non-compliant protective masks mostly included protective mask recalls and recalls from end users.

A statistically significant relationship was found between the differentiating factors and the years of the COVID-19 pandemic. Only in the case of the frequency of voluntary measures existing in the notifications, which involves no marketing authorisation granted, was no statistically significant relationship found.

In the case of protective masks, especially in the context of pandemic COVID-19, the Safety Gate/RAPEX system played an important role in monitoring and recalling unsafe products from the market. It is nevertheless recommended that Member State regulators take measures to improve the quality of notifications submitted. Well-documented notifications expedite public outreach and effective recalls of dangerous products. The COVID-19 pandemic highlighted weaknesses in the market surveillance system and increased the need for reform. Recommendations related to enhancing the notification system are confirmed by the European Commission's actions and the modernisation of the Safety Gate early warning system, as foreseen by EU Regulation 2023/988 on general product safety (GPSR).

Authors' Contribution

The authors' individual contribution is as follows: Joanna Wierzowiecka 95%, Victoria Dąbrowska 5%.

Conflict of Interest

The authors declare no conflict of interest.

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