IJBPAS, June, 2024, 13(6): 2603-2613

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

AN OVERVIEW OF PRE AND POST PANDEMIC REGULATORY CHANGES FOR RESPIRATORS IN USA AND EUROPE

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Received 15th April 2023; Revised 8th June 2023; Accepted 1st Sept. 2023; Available online 1st June 2024

https://doi.org/10.31032/IJBPAS/2024/13.6.8025

ABSTRACT

The use of medical masks and respirators as personal protective equipment is critical in decreasing the amount of biological hazard to healthcare personnel which are exposed during outbreaks of highly spreadable diseases such as recently discovered SARS-CoV-2 coronavirus. The COVID-19 pandemic, which began in 2020, has significantly increased the demand for personal protective equipment (PPE) because it acts as one of the methods of reducing coronavirus transmission. Despite of coronavirus vaccines availability, the Center for Disease Control and Prevention (CDC) and European centre for disease prevention and control (ECDC) and the World Health Organization (WHO) still recommends PPE, as well as the production has also increased in order to satisfy demand and as a result, some inferior products also entered the market. Many types of Personal Protective Equipment (PPE), particularly surgical N95 filtering facepiece respirators (FFRs), have been seriously damaged by the COVID 19 pandemic. As a result, the food and drug administration (FDA) and European medicines agency (EMA) has granted an Emergency Use Authorization (EUA) allowing the use of industrial N95 respirators as well as the importation of N95-masks which meets the international requirements such as KN95 masks from China and FFP2 masks from the European Union. The main aim is to provide comparative regulatory changes implemented in respirators because of COVID 19 scenario.

Keywords: Respirators, COVID 19, USA, EUROPE, Regulatory changes

INTRODUCTION

The US Centers for Disease Control and Prevention (CDC), the European Centre for Disease Prevention and Control (ECDC), and the World Health Organization (WHO) frequently recommend respirators at least as protective as a N95, FFP2, or similar particulate respirator when respiratory protection is recommended to help reduce exposure to biological hazards **[1, 2]**. The FDA and EMA are committed to providing timely guidance to aid in the pandemic response. Since the COVID 19 outbreak, there is rise in applied research and development to improve respirators in terms of standard testing, new standard and non-standard procedures and speed up the certification process. For instance, since March 2020, expired respirators and the use of various decontamination processes have been approved for use in order to extend the use of respirators **[3]**. The pandemic has resulted into increase in the demand for personal protective equipment (PPE) around the world as a result of the increased demand, some improper PPE has been sold, which is unfit for use because it do not fulfil standards or legislation.

Respirator in USA and Europe:

In USA, there are Many different types of filtering facepiece respirators have been approved by NIOSH. N95 respirators are the most readily accessible, but other types (N99, N100, P95, P99, P100, R95, R99, and R100) provide similar or better protection **[4]**. Employers who want to give their employees N95 respirators must follow an Occupational Safety and Health Administration (OSHA) respiratory protection programme **[5]**. However, In Europe, the abbreviation FFP stands for "filtering face piece." It is a European standard for mask efficiency that ranges from one to three, with one being the lowest and three being the highest. FFP2 masks filter at least 94% of all aerosols, including viruses like covid-19 that are spread through the air **[6]**.

Table: 1 Standard and filtration effectiveness of respirators in USA and Europe

Sr. No.	Standard	Filtration Effectiveness		
1	USA: NIOSH (42CFR Part84)	N95/ Surgical N95	N99	N100
		0.3 microns: ≥95%	0.3 microns≥99%	0.3 microns: ≥99.97%
2	Europe: EN149:2001	FFP1	FFP2	FFP3
		0.3 microns: ≥ 80%	0.3 microns: ≥ 94%	0.3 microns: ≥ 99%

0.3 Microns: used to represent the most - penetrating particle size (MPPS), which is the most difficult particle size to capture

What is the reason behind the shortage of respirators during COVID 19?

A lack of meltblown fabric, the essential filtration material used in the devices, and a lengthy and costly clearance and

certification process for new producers are two major roadblocks to boosting N95 respirator production. Respirator manufacturing is typically highly mechanised. Respirators are made up of multiple layers of meltblown and spunbond fabric that are fed into machines, moulded, and cut into the required mask shape. Before they are packaged, the nose bridge and straps are affixed, normally by machine but occasionally by hand. Vertical integration varies in respirator manufacturing, with some companies (such as 3M) producing several components in-house and others outsourcing inputs **[7]**. Polypropylene meltblown nonwoven fabric is the primary filtering material of the N95 respirator; spunbond fabric is also an important component. Steel staples and aluminium nose clips are required, as well as raw materials for the inputs, such as polypropylene for the shell, polyurethane for the nose foam, and polyisoprene for the straps.

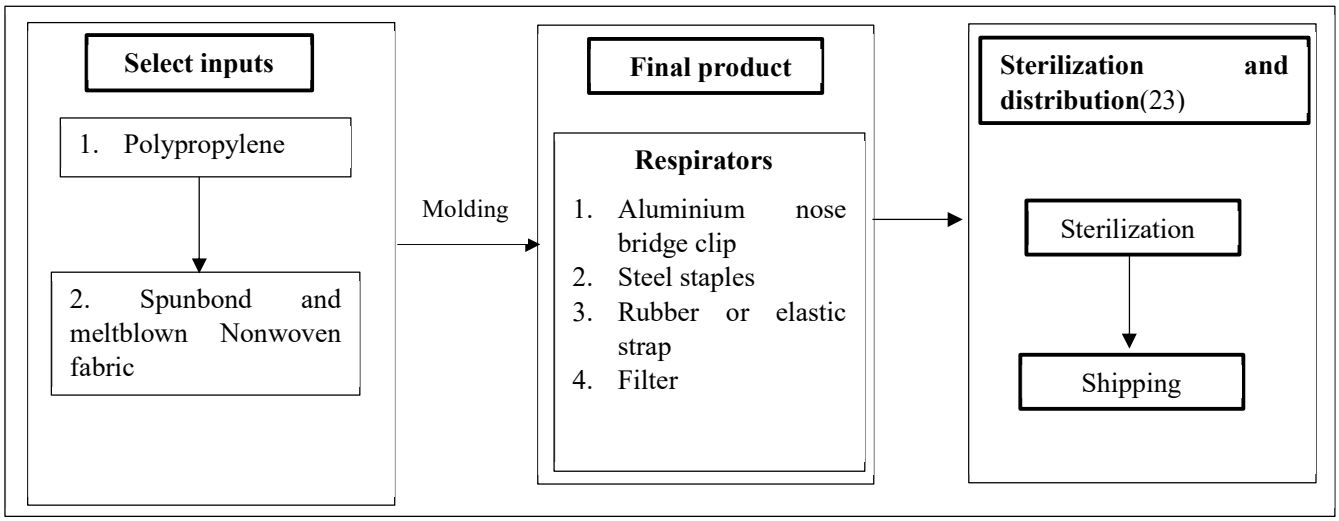


Figure 1: Identifying key inputs and components that have produced supply chain issues and limits through packaging for N95 respirators

Regulatory changes of respirators in USA:

Table 2: Regulatory changes of respirators in USA

Sr. No.	Criteria	Pre Covid 19	Covid 19
1	Product code	They do not provide any product code to respirators(8)	They provide product code to respirators.
2	Strategies	Before covid 19 there is no Strategies for Optimizing the Supply of N95 Respirators	After covid-19 there is Strategies for Optimizing the Supply of N95 Respirators [9]
3	Decontaminati on system	Not specified	Decontamination system has been implemented(3)
4	Substitute	Before covid 19 there is a no need of N95 FFR substitute in market.	During covid-19 N95 FFR substitute has been a PAPR100 to the marketplace [10]
5	Guideline	Before covid 19 it is Non powered air purifying respirators.	In the guideline of 42CFR part84 the change in the subpart K name is change from non powered air

			purifying particulate respirators to Air purifying respirators [11].
6	**NIOSH**	**Before covid 19 there are only NIOSH certified respirators are sold in market.**	**As emergency use authorization they approved the non-NIOSH approved respirators [12].**
7	**Standard**	**Emergency temporary standard is not there before covid 19**	**To protect health-care employees, the Emergency Temporary Standard (ETS) mandates employers to supply NIOSH-approved or FDA-authorized respirators to personnel who may be exposed to COVID 19 [13].**
8	**Approval process**	**A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective is necessary.**	**As an emergency use authorization, the respirators are approved without the 510k approval application [14].**
9	**Purpose**	**Not specified**	**FDA will consider its for medical purpose if it is 1) they are labelled or otherwise meant for use by a healthcare professional; 2) they are labelled or otherwise intended for use in a healthcare facility or setting; and 3) they include all medicines, biologics, and antimicrobial/antiviral agents [8].**
10.	**Recommendations**	**Before Covid 19 there is a no need to re-use or decontaminate the disposable PPE.**	**No recommendations were released about the re-use or decontamination of disposable PPE.**
11.	**Upgradation of decontamination system**	**Before COVID 19 the decontamination methods are ultraviolet germicidal irradiation, microwave-generated steam, and moist heat**	**Increase in number of decontamination systems are Vaporous hydrogen peroxide, ultraviolet germicidal irradiation, and moist heat, use of autoclave, 160 ◦C dry heat, 70% isopropyl alcohol, microwave irradiation, bleach and soap and water, because they could affect the filtering performance [3]**
12.	**OSHA Guideline**	**Before COVID 19 there is no requirement to issued a memorandum for use the same model, style and size of respirators that was tested the first time.**	**During the COVID 19 national emergency, OSHA issued a memorandum suspending the yearly fit test requirement as long as employees continue to use the same model, style, and size respirator that was tested the first time [5]**
13.	**Email id**	**Not specified**	**COVID 19 FDAIMPORTINQUIRIES@fda.hhs.gov, is a unique email address set up by the FDA for industry representatives to rapidly connect with the agency and resolve inquiries or concerns [12].**
14.	**Standard**	**There is no standard for reusable medical device**	**In February 2021, ASTM International issued ASTM F3502-21, which specifies single and reusable non-medical barrier face coverings; the standard was produced by ASTM International's subcommittee F23.65 for respiratory protection.**

Regulatory changes of respirator in EUROPE:

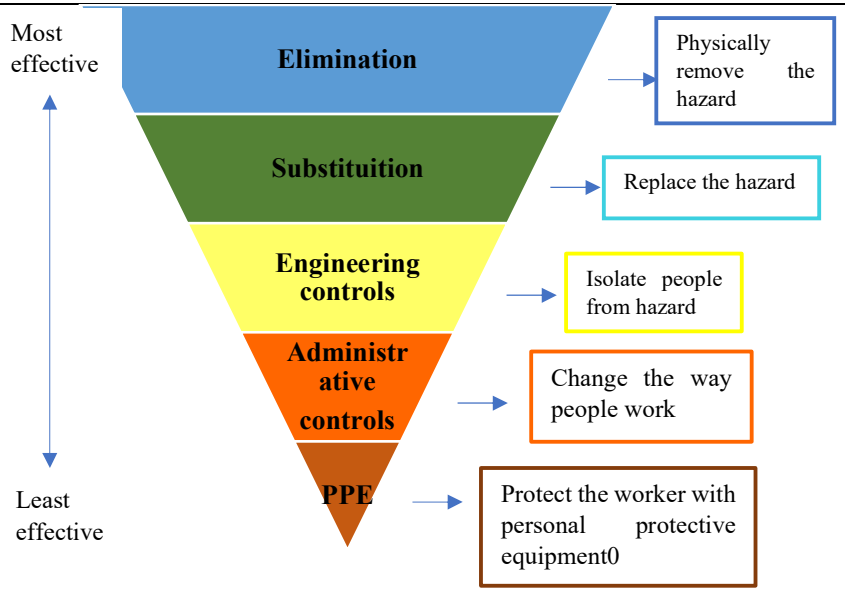
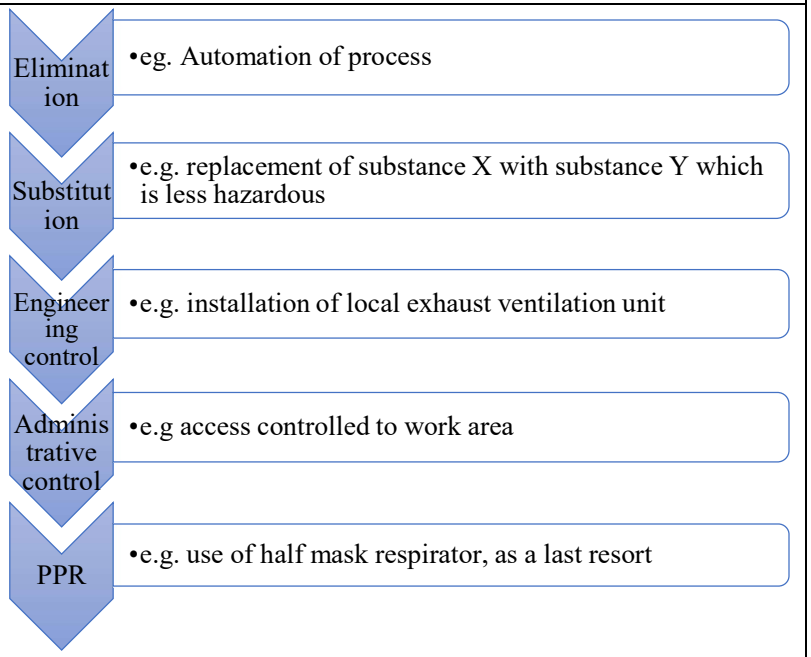
Table 3: Regulatory changes of Respirators in Europe

Sr. No.	Criteria	Pre- COVID 19	After- COVID 19
1	**Regulation**	**Under the Old directive of EU 2016/425 employers had to ensure the correct suitability, provision, maintenance and use of PPE.**	**A transition period of a year was mandated to manufacturers and as of the end of April 2019, no more PPE can be sold or manufactured that does not comply with Regulation (EU) 2016/425. Whereas under the old directive, employers had to ensure the correct suitability, provision, maintenance and use of PPE, the new regulation makes the whole supply chain accountable [15].**
2	**Economic operators**	**-**	**Economic operators are revamping their supply chains to offset the consequences of numerous disruptive variables by opening new manufacturing lines and/or diversifying their supplier base.**

3	**(EU) 2016/425**	**Not specified in before Covid 19 regulation.**	**PPE manufactured in compliance with Regulation (EU) 2016/425 is free to circulate throughout the internal market, and Member States are not allowed to impose extra and divergent restrictions for its manufacture and placement on the market [15].**
4	**Economic operators and interested parties**	**Economic operators and interested parties are not involved previously.**	**The demand for specific devices and equipment has risen rapidly as a result of the extraordinary conditions, resulting in the involvement of economic operators and other interested parties who were not previously involved in the supply and verification chain of these items [16].**
5	**Procurement procedures**	**No procurement procedure previously.**	**A procurement procedure for personal protective equipment has been begun under the Joint Procurement Agreement for medical countermeasures, in accordance with the Council Conclusions of the Health Ministers Council on 13 February 2020. It might be finalised as early as the first week of April, according to an estimated timeline and market conditions.**
6	**New regulations**	**-**	**EU commission published Recommendation EU 2020/403.**
7	**Support guideline**	**Not available**	**Conformity assessment procedures for protective equipment [16].**
8	**Changes in standards**	**European standards are copyright-owned by the European standardisation organisations which have developed by (CEN) & (CENELEC). Normally, manufacturers must purchase the standards they need from the national members of the European standardisation organisations, i.e. the national standardisation bodies.**	**The Commission agreed with the European standardisation organisations CEN and CENELEC that a set of standards (including EN 149 and EN 14683) are exceptionally made freely and fully available by the national standardisation bodies.**
9	**CE marking**	**The CE marking is the final stage, marking the culmination of all procedures prior to the placing of the product on the market.**	**The CE marking should normally be affixed by the manufacturer once the first sample of the product has been assessed and approved by the notified body [17].**

Comparison of Regulatory changes of respirators in USA and Europe

Table: 4 Comparisons of regulatory changes of respirators in USA and Europe

Sr. No.	CRITERIA	USA	EUROPE
1	Name of respirators	Respiratory protective devices	Respiratory protective equipment
2	Standards(7)	ASTM F3502 21	EN149
3	Preventive measures / strategies		

4 **Filter class**

Class of filter(18)	Efficiency%	Test agent	Test maximum loading (mg)	Type of contaminant
N -series		NACL	200	Solid and water-based particulates (i.e., non-oil aerosols)
N100	99.97			
N99	99			
N95	95			
R-Series		DOP oil	200	Any
R100				
R99				
R95				
P- Series		DOP oil	Stabilized efficiency	Any
P100				
P99				
P95				

Note: NACL: sodium chloride

- **High (200 mg) filter loading in the certification test is intended to address the potential for filter efficiency degradation by solid or water-based aerosols in the workplace.**
- **DOP oil = dioctyl phthalate.**
- **N for Not resistant to oil,**
- **R for Resistant to oil**
- **P for oil Proof**

class	Filter penetration limit (at 95 L/min air flow) (19)	Inward leakage	Typical elastic band
FFP1	Filters at least 80% of airborne particles	<22%	Yellow
FFP2	Filters at least 94% of airborne particles	<8%	Blue or white
FFP3	Filters at least 99% of airborne particles	<2%	Red

5	**Fit testing**	**Qualitative fit testing: A qualitative fit test (QLFT) relies on the respirator wearer's senses to determine if there is a gap in the seal of the respirator to the wearer's face. The OSHA-accepted fit test protocol provides complete instructions for conducting QLFTs with the accepted test agents. Note: NIOSH does not endorse or recommend the use of the irritant smoke fit test.** **Quantitative fit testing: A quantitative fit test uses a fit testing instrument(s) to provide quantitative, or numerical, measurements of the amount of face seal leakage present when a user wears a respirator. It requires a hole punched in the respirator to perform the test. Therefore, the fit tester must dispose of the respirator after the test [20].**	**Qualitative fit testing: in which subjective odours or tastes must be sensed by the person being fit tested. This method can be very tedious and time-consuming if the respirator does not fit.** **Quantitative fit testing: in which an instrument collects objective data and provides a clear measurement of the respirator's fit.(21)**
6	**Regulation**	**Occupational Safety and Health Administration [5]**	**Occupational safety and health [22]**
7	**Inhalation resistance – max pressure drop**	**≤ 343 Pa**	**≤ 70 Pa (at 30 L/min)** **≤ 240 Pa (at 95 L/min)** **≤ 500 Pa (clogging)**
8	**Exhalation resistance - max pressure drop**	**Leak rate ≤ 30 mL/min**	**N/A**
9	**CO2 clearance requirement**	**N/A**	**≤ 1%**

CONCLUSION:

There were constraints on mass production in manufacturing during the pandemic, as well as an inability to develop inexpensive and effective respirators to meet public demand. Lack of scientific data, inability to meet demand at reasonable prices, and inability to manufacture the filtering material (e.g., meltblown fabric), as well as the presence of uncertainty parameters in predicting FEs under various environmental conditions, all hampered respirator production during the first wave of the pandemic. In the case of respirators, there are also some regulation adjustments in the United States and the European Union. In nut shell the main purpose of both the country is to increase the production of respirators and decontaminate the respirators, also put the respirators in the category of emergency use authorization by doing this they focused on increasing the supply chain of respirators in current pandemic scenario.

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