May, 2020

AEPC Study on Capacity of PPE Manufacturing

Content

Overview

Due to COVID-19 pandemic there is a huge demand of PPE kits all across the world. Besides the frontline healthcare workers, the PPE products are required by the staff and other paramedical staff. In many countries, including India, Masks have been made mandatory in public spaces.

PPE kit include items such as gowns, respirators, face masks, safety-footwear harnesses, eye protection gear and gloves.

Based on WHO modelling, an estimated 89 million medical masks are required for the COVID-19 response each month. For examination gloves, that figure goes up to 76 million, while international demand for goggles stands at 1.6 million per month and WHO also recommended that to meet rising global demand, the industries must increase manufacturing by 40 per cent. The projected demand of PPE kit in India is 2.06 crore by June 2020 (as per secondary research).

India has ramped up its production of PPE kit and has achieved an unprecedented goal of producing 1.5 lakh PPE kits daily (as per secondary research). This has been achieved with nearly no domestic manufacturing of PPE kit in the country till a few months back, with majority of the demand being met through imports.

An important element of the PPE market is the standards that the products follow, especially for the medical grade products. For the same, the infrastructure for testing has been rapidly increase in the last few months.

Presently, South Indian Textile Research Association, Coimbatore, Defense Research & Development Establishment, Gwalior now at INMAS (DRDO) laboratory at Delhi., Heavy Vehicles Factory, Avadi, Tamil Nadu, Small Arms Factory, Kanpur, UP, Ordnance Factory at Muradnagar (UP), Kanpur(UP) and Ambernath (Maharashtra) and Metal and steel factory, Ishapore (West Bengal) are all equipped for conduction testing, certification and quality control procedures required in connection with PPE Body Coveralls required for COVID-19 (as per Ministry of Textile's order no. F. No. 8/4/2020-R&D dated 30th April).

Recognizing the opportunity that this emerging sector has, not only for meeting the immediate need of the nation, but also for future exports, the Government of India has been introducing several policy support measures for facilitating growth of this sector. Some of the state governments have also initiated efforts to encourage development of this industry in the state.

Details of the policy environment in India for production of PPEs is at Annex 1

The PPE products need to follow stringent standards – for the material used, as also the functionalities of the finished products. India has been following the WHO standards, besides some private standards, so far. The Bureau of India Standards (BIS) is also in developing standards for the PPE products.

For the export market, different countries have different health and safety standards prescribed that need to be followed.

Understanding the Global Market of PPE

Major Suppliers of PPE.

Major suppliers of PPE kits are China, Malaysia, Vietnam, Thailand and Germany, where China holds the largest share. Vietnam has also shown a good positive growth in the year 2019 as compared to the previous year.

Global Top 5 Exporters of PPE

S. No.	Exporters	Export in USD mn.		% Change (2018/2019)	% Share	
		2018	2019		2018	2019
	World	**28599.2**	**29639.8**	**3.6**	**100**	**100**
1	China	8733.6	8653.4	-0.9	30.5	29.2
2	Malaysia	4548.0	4346.5	-4.4	15.9	14.7
3	Viet Nam	1089.0	1573.5	44.5	3.8	5.3
4	Thailand	1392.3	1453.6	4.4	4.9	4.9
5	Germany	1401.1	1415.6	1.0	4.9	4.8

Source: UN Comtrade, 2020

Major Importers of PPE

The top five countries that import PPE products are listed below. As indicated, USA is the largest country with 28.2% share, while EU is the largest region with 37% share. In Eu, Germany, France and UK are the largest markets. Japan is another big market, which can be tapped, given our FTA status with Japan.

Global Top 5 Importers of PPE						
S. No.	Exporters	Import in USD mn.		% Change (2018/2019)	% Share	
		2018	2019		2018	2019
	World	**28605.4**	**29266.8**	**2.3**	**100**	**100**
	EU (28)	**10641.1**	**10905.5**	**2.5**	**37.2**	**37.3**
1	United States of America	7950.6	8248.7	3.7	27.8	28.2
2	Germany	2188.3	2221.4	1.5	7.6	7.6
3	Japan	1448.3	1464.6	1.1	5.1	5.0
4	France	1339.0	1362.7	1.8	4.7	4.7
5	United Kingdom	1159.2	1167.8	0.7	4.1	4.0
Source: UN Comtrade, 2020						

India's exports of PPE products have been stagnant in the last few years, as indicated in table below. Also, India has been supplying basic products and has limited exports to the larger PPE markets in USA and EU. This can be because of the standards and certifications required and the non availability of the right fabrics and technology needed for servicing these western markets.

India's PPE Exports in January, 2020 & Top Export Destination for PPE Kits :

India's PPE Kits Exports to World in January, 2020

India's PPE Kits Exports to World					
S. No.	HS Code	Products	In USD Mn.		% Change
			January, 2019	January, 2020	
		Total	**48.2**	**33.6**	**-30.4**
1	401511	SURGICLE GLOVES,MITTENS AND MITTS	2.5	3.1	25.2
2	401519	OTHER GLOVES,MITTENS AND MITTS	0.3	1.2	290.3
3	611610	GLOVES MITTENS AND MITTS IMPREGNATED COTD/ COVRD WTH PLSTC/RUBR, KNITD/CROCHTD	1.4	1.7	27.0
4	621010	GARMENTS,MADE UP OF FABRICS OF HEADING NO.5602 OR 5603	0.4	0.7	65.0

India's PPE Kits Exports to World					
S. No.	HS Code	Products	In USD Mn.		% Change
			January, 2019	January, 2020	
		Total	**48.2**	**33.6**	**-30.4**
5	621050	OTHER WOMEN?S OR GIRLS? GARMENTS	0.2	0.1	-35.3
6	630790	OTHER MADE UP ARTICLES	42.4	25.4	-40.1
7	900490	OTHER SPECTACLES,GOGGLES ETC	1.1	1.4	24.6
Source: DGCI&S,Kolkata, 2020					
Note: The above items have been identified as PPE as per Trademap identification of medical items					

India's Top 25 Export Destination for PPE Kits					
S. No.	Importers	In USD Mn.			% Change
		2017	2018	2019	
	World	**664.5**	**545.7**	**494.7**	**-9.3**
	Top 25	**562.6**	**450.6**	**425.1**	**-5.7**
1	United Arab Emirates	68.3	84.0	70.7	-15.8
2	Nigeria	27.9	47.1	69.7	48.0
3	United States of America	238.7	75.2	65.0	-13.5
4	Bangladesh	4.7	12.1	26.5	118.7
5	United Kingdom	31.6	20.5	16.7	-18.7
6	Germany	21.3	12.3	15.5	26.2
7	France	15.1	14.1	13.7	-2.4
8	Japan	8.8	9.8	12.0	21.8
9	Afghanistan	6.3	22.3	11.1	-50.5
10	Saudi Arabia	3.9	3.7	10.7	186.2
11	Pakistan	12.9	21.1	10.6	-49.7
12	Netherlands	8.7	5.8	9.9	72.6
13	Kenya	11.6	8.4	9.5	13.7
14	Australia	10.8	9.9	9.4	-5.5
15	Sri Lanka	15.3	7.5	9.3	24.0
16	Belgium	7.5	9.6	8.7	-9.1
17	Canada	5.5	5.0	8.6	71.8
18	Spain	8.8	6.9	7.1	3.2

India's Top 25 Export Destination for PPE Kits					
S. No.	Importers	In USD Mn.			% Change
		2017	2018	2019	
	World	**664.5**	**545.7**	**494.7**	**-9.3**
	Top 25	**562.6**	**450.6**	**425.1**	**-5.7**
19	Iran, Islamic Republic of	11.6	32.3	7.1	-77.9
20	Togo	7.0	10.4	6.3	-39.8
21	Italy	9.2	6.0	6.1	0.8
22	Tanzania, United Republic of	14.2	9.7	5.9	-39.4
23	Poland	3.8	4.3	5.8	32.8
24	Malaysia	6.2	10.1	5.3	-47.9
25	Israel	2.6	2.4	3.8	57.7
Source: UN Comtrade, 2020					

Quality and regulatory framework:

Standardization is the process of developing and implementing technical standards.

Standardization helps to maximize safety, quality, repeatability, etc... It can also facilitate commoditization of formerly custom processes.

The PPE is divided in product families, for each of the product families there are several standards. Standards are National, Regional or International eg.

- EN = regional: for Europe
- ISO = International
- EN/ISO combination: applicable as well in Europe as International.

The detailed list of standards is at Annex 2

EU-

In EU Regulation (EU) 2016/425 of 9 March 2016 on PPE are the regulations that covers design, manufacture and marketing of PPE. These are legal obligations that provide the ensure to provide the highest level of protection against risks in the EU internals market. Standardization of PPE provides a list of references of harmonized European standards under the PPE regulation.

Regulation (EC) No 765/2008 of the European Parliament and of the Council lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions concerning procedures to deal with PPE presenting a risk should be adapted to that Decision.

In order to ensure as high a level of protection for the user of those products as for the user of PPE covered by Directive 89/686/EEC, the scope of this Regulation includes PPE for private use against heat, in line with similar PPE for professional use which is already covered by Directive 89/686/EEC.

Compliance with the EU legislation on PPE (Regulation (EU) 2016/425) ensures that PPE are safe to be used by the wearer and at the same time offer the necessary and claimed protection. Having the same legislation in the EU (+EFTA/EEA and some other European countries) is obviously a key element for the single market.

The conformity assessment procedure is the responsibility of the manufacturer of the PPE. First step is to make a risk analysis, defining what protection is offered by the product and what the foreseeable use (and misuse) is. Based on this, the category of the PPE is defined (for instance for respiratory protection that is always category III). In the case of category II and III PPE (which are the vast majority of PPE), the manufacturer must apply for a type examination by a Notified Body which results in an EU Type Examination Certificate. For category III PPE (such as protective masks), this also needs to be completed with a follow-up of the production by a Notified Body.
Once this completed, the manufacturer has to mark the product with the CE mark (in case of category III followed by the number of the Notified Body responsible for the production follow-up) together with his name (and address), the reference of the product and reference of the standard used (for full list of what needs to be included in the marking, see the Regulation, e.g. article 8 (obligations of manufacturers) and also the (European) standards).

The manufacturer must prepare the Declaration of Conformity which needs to be included with each product (or at least a link to the document must be available with the product) and ensure that procedures to remain in conformity are in place for the series production of the PPE. This Declaration of Conformity is the only document that needs to accompany the PPE and that the manufacturer needs to share with his customers.

All PPE have to be accompanied by the instructions for the user in the language of the country where the PPE will be sold

United States of America (USA)-

In USA all the PPE required for their healthcare workers must follow FDA regulations and must meet specific performance standards for protection. FDA has established Quality systems Regulations and Good Manufacturing Practices.

Manufacturers in USA are expected to use these regulations and practices for maintaining product quality and to conform to the standards.

Certification Body- BSI Group

Notified bodies and accreditation bodies:

The Notified Bodies have an important role in the conformity assessment of PPE. Different countries have their own notified bodies for conformity assessment of PPEs like. The list of notified bodies for some of the major importing countries is at **Annex 3.**

Similarly, different countries have their accreditation bodies for certifying to the laid standards. List of such certifying bodies is **at Annex 4**.

In order to enhance the harmonization of the work of the Notified Bodies, the EU Commission support the European Coordination group. The Committees under it deals with questions related to the implementation of the legislation when it comes to certification (both type examination and quality module C2 or D), certification of specific product groups, testing according to the relevant standards, or with certification in case where there are no standards available.

Present Situation in India

Presently, in India, South Indian Textile Research Association, Coimbatore, Defense Research & Development Establishment, Gwalior now at INMAS (DRDO) laboratory at Delhi., Heavy Vehicles Factory, Avadi, Tamil Nadu, Small Arms Factory, Kanpur, UP, Ordnance Factory at Muradnagar (UP), Kanpur(UP) and Ambernath (Maharashtra) and Metal and steel factory, Ishapore (West Bengal) are all equipped for conduction testing, certification and quality control procedures required in connection with PPE Body Coveralls required for COVID-19 (as per Ministry of Textile's order no. F. No. 8/4/2020-R&D dated 30th April).

Below are the technical specifications of medical supplies given by HLL are as below:-

a) Personal Protective Coverall (Garments) - along with shoe cover - option 1

• Impermeable to blood and body fluids

• Single use

• Avoid culturally unacceptable colors e.g. black.

• Light colors are preferable to better detect possible contamination

• Thumb/finger loops to anchor sleeves in place

• Quality compliant with following standard a. Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent b. EN 14126 (barrier to infective agents) certified.

b) Personal Protective Coverall (Garments) with Tape over seam along with shoe cover - option 2

• Single use

• Avoid culturally unacceptable colours e.g. black

• Light colours are preferable to better detect possible contamination

• The Fabric, Garment/Coverall and Seam should pass Synthetic Blood Penetration test at SITRA, Coimbatore. Manufactures/suppliers submitting the pass certificate as above would be qualify.

• Coverall shall be designed to be universal Fit

• Coverall shall have in built Hood Cap

• Zipper of the coverall shall be covered with a flap to avoid accumulation of microbes

• Soft Elastic to be fitted around Front of hood, wrists & ankles

• Boot Cover: Pair of Boot Covers made of same fabric as of Coverall Soft elastic to be fitted at two levels, ankle and end

c) **Goggles**

• With transparent glasses, Zero power, well fitting, covered from all sides with elastic band/or adjustable holder.

• Good seal with the skin of the face.

• Flexible frame to easily fit all face contours without too much pressure.

• Covers the eyes and surrounding areas and accommodates for prescription glasses.

• Fog and scratch resistant.

• Adjustable band to secure firmly so as not to become loose during clinical activity.

• Indirect venting to reduce fogging.

• May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable.

• Quality compliant with the below standards, or equivalent: a. EU standard directive 86/686/EEC, EN 166/2002 b. ANSI/SEA Z87.1-2010

d) **N-95 Masks**

• Shape that will not collapse easily

• High filtration efficiency

• Good breathability, with expiratory valve

• Quality compliant with standards for surgical N95 respirator: a. NIOSH N95, EN 149 FFP2, or equivalent

• Fluid resistance: minimum 80 mmhg pressure based on ASTM F1862, ISO 22609, or equivalent.

• Quality Compliant with standards for particulate respirator that can be worn with full-face shield

Nitrile Gloves (Size 6.5, 7 & 7.5)

• Nitrile

• Non-sterile

• Powder free

• Outer gloves preferably reach mid-forearm (minimum 280mm total length)

• Different sizes (6.5, 7 & 7.5)

• Quality compliant with the below standards, or equivalent: a. EU standard directive 93/42/EEC Class I, EN 455 b. EU standard directive 89/686/EEC category III, EN 374 c. ANSI/SEA 105-2011 d. ASTM D6319-10

e) **Face Shield**

• Made of clear plastic and provides good visibility to both the wearer and the patient

• Adjustable band to attach firmly around the head and fit snuggly against the forehead

• Fog resistant (preferable)

• Completely covers the sides and length of the face

• May be re-usable (made of material which can be cleaned and disinfected) or disposable

• Quality compliant with the below standards, or equivalent: a. EU standard directive 86/686/EEC, EN 166/2002 b. ANSI/SEA Z87.1-2010

f) **Triple Layer Surgical mask with elastic band**

Three layered surgical masks of non-woven material with nose piece, having filter efficiency of 99% for 3 microns particle size.

A. ISO 13485 / ISO 9001 / EN14683 or equivalent

Background of the AEPC Study

AEPC has conducted a study on current situation of PPE manufacturing of AEPC members. We have received 174 responses till 2020/05/10 from our members and the responses have been analyzed.

Objective

i. To assess the situation of PPE manufacturing and plans of exporters to manufacturer PPE
ii. To assess the capacity of PPE manufacturing
iii. To understand the market of PPE

1. **Do you manufacture PPE kits?**

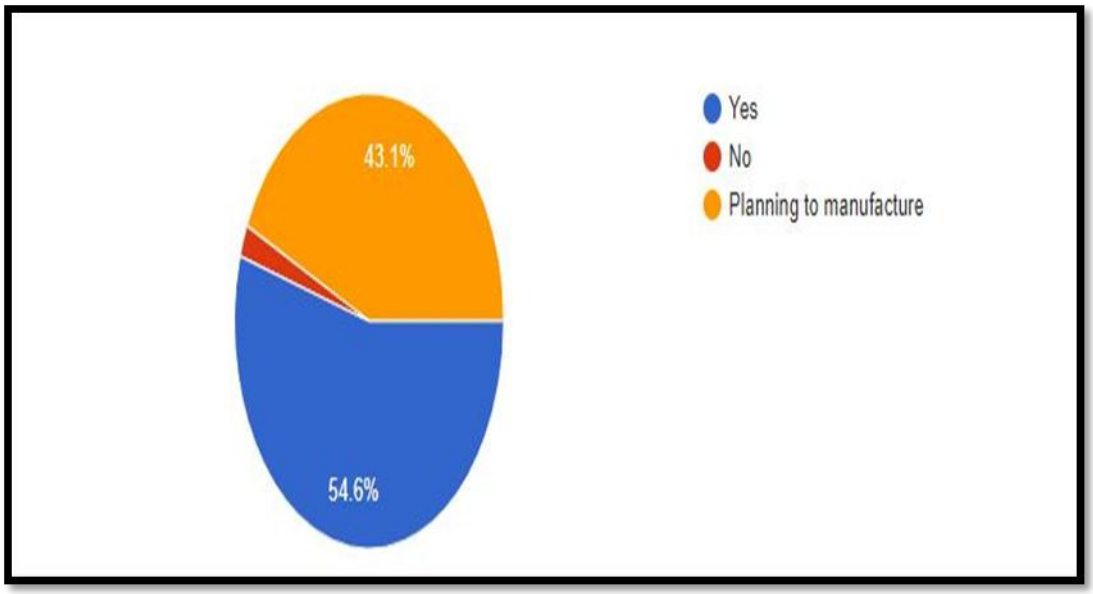

Fig. 1

As per Fig. 1,

I. 54.6% of the respondents have indicated that they manufacture PPE kits.

II. 2.3% of the respondents have indicated that they do not manufacture PPE kits.

III. 43.1% of the respondents have indicated that they are planning to manufacture PPE kits.

2. **If planning to manufacture, when are you planning to start the manufacturing?**

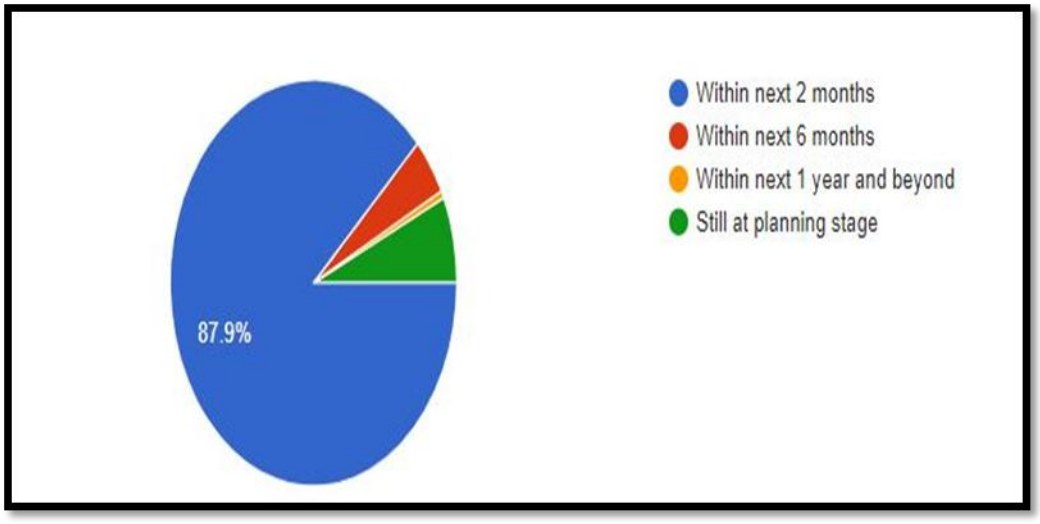

Fig.2

As per Fig. 2,

I. 87.9% of the respondents have indicated that they are planning to start the manufacturing within next 2 months.

II. 4% of the respondents have indicated that they are planning to start the manufacturing within next 6 months.

III. 0.6% of the respondents have indicated that they are planning to start the manufacturing within next 1 year and beyond.

IV. 6.9% of the respondents have indicated that they are still at planning stage.

3. What capacity you are planning to manufacture?

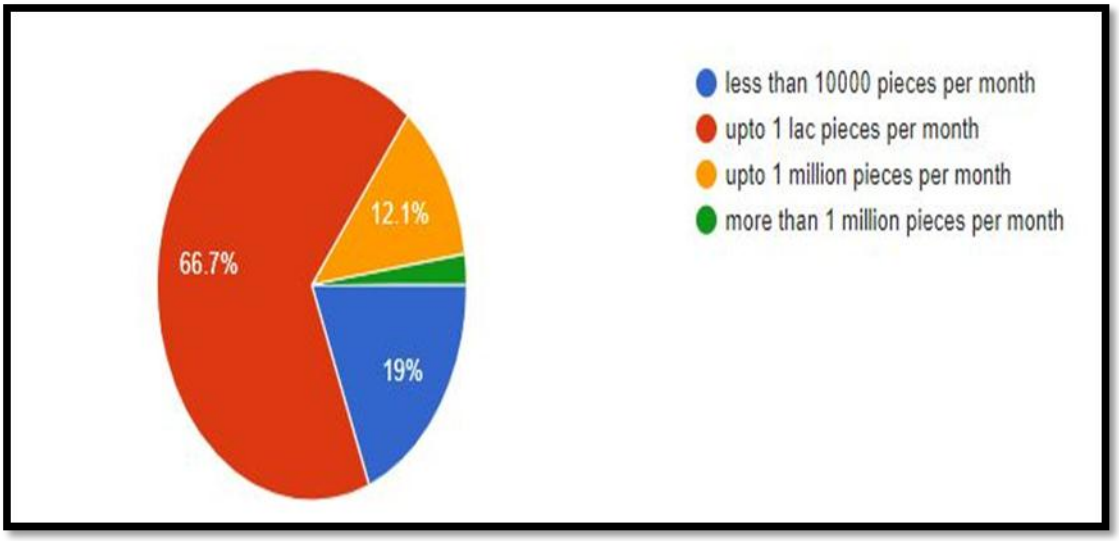

Fig.3

As per Fig. 3,

I. 66.7% of the respondents have indicated that they are planning to manufacture less than 10000 pieces per month.

II. 19% of the respondents have indicated that they are planning to manufacture up to 1 lac pieces per month.

III. 12.1% of the respondents have indicated that they are planning to manufacture up to 1 million pieces per month.

IV. 2.2% of the respondents have indicated that they are planning to manufacture more than 1 million pieces per month.

4. Which of the following products do you manufacture?

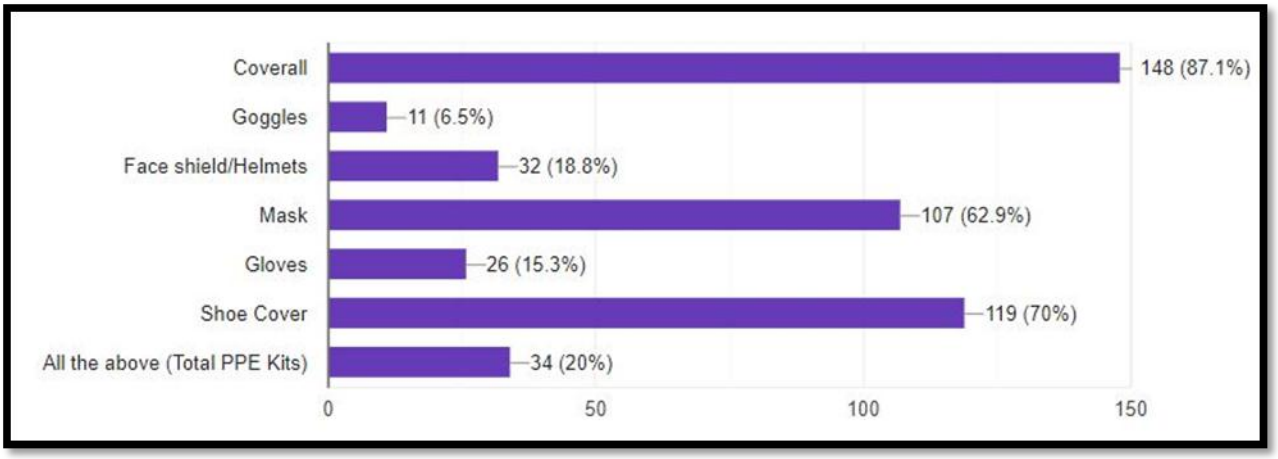

Fig.4

As per Fig. 4,

I. 148 respondents have indicated that they manufacture Coverall.
II. 11 respondents have indicated that they manufacture Goggles.
III. 32 respondents have indicated that they manufacture Face shield/Helmets.
IV. 107 respondents have indicated that they manufacture Gloves.
V. 119 respondents have indicated that they manufacture Shoe cover.
VI. 34 respondents have indicated that they manufacture complete PPE kit.

5. Are you following WHO specifications?

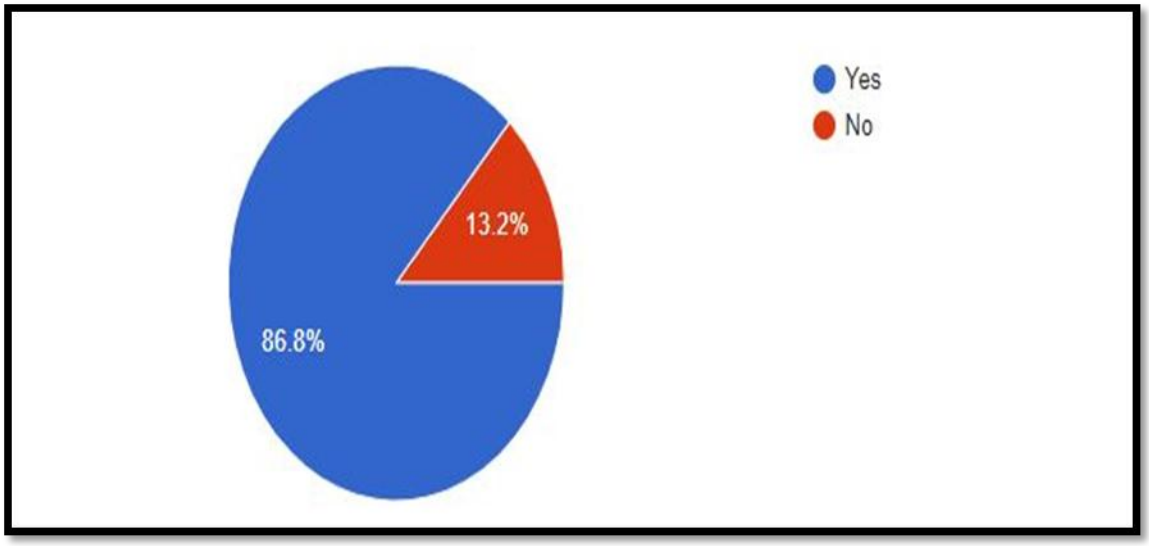

Fig.5

As per Fig.5,

I. 86.8% of the respondents have indicated that they are following WHO specifications.
II. 13.2% of the respondents have indicated that they are not following WHO specifications.

6. What is your current market of PPE?

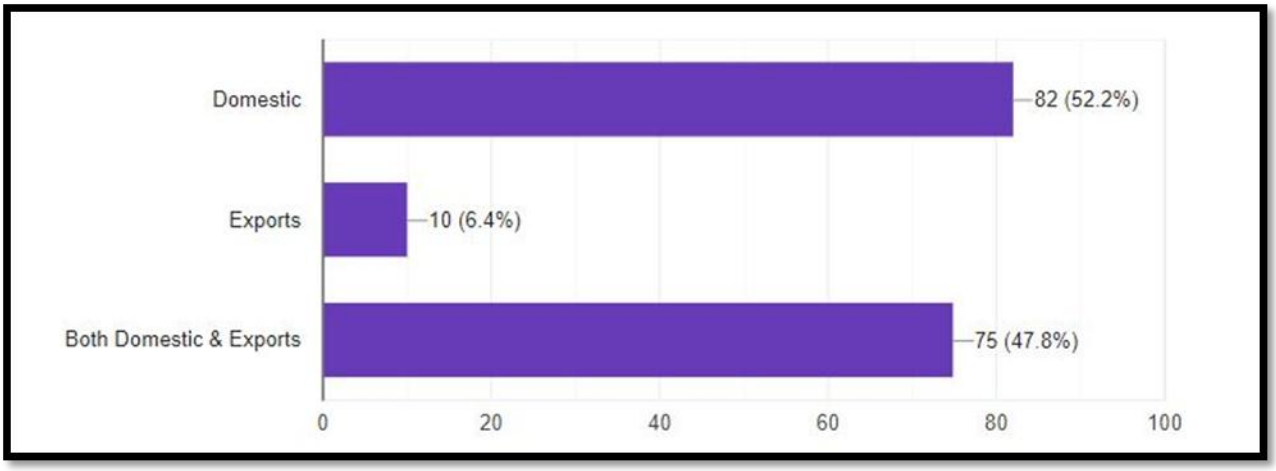

Fig.6

As per Fig. 6,

I. 82 respondents have indicated that their current market of PPE is domestic.

II. 10 respondents have indicated that their current market is exports.

III. 75 respondents have indicated that their current market of PPE is both domestic and exports.

7. **What is your production capacity per month of Coverall? (In pieces)**

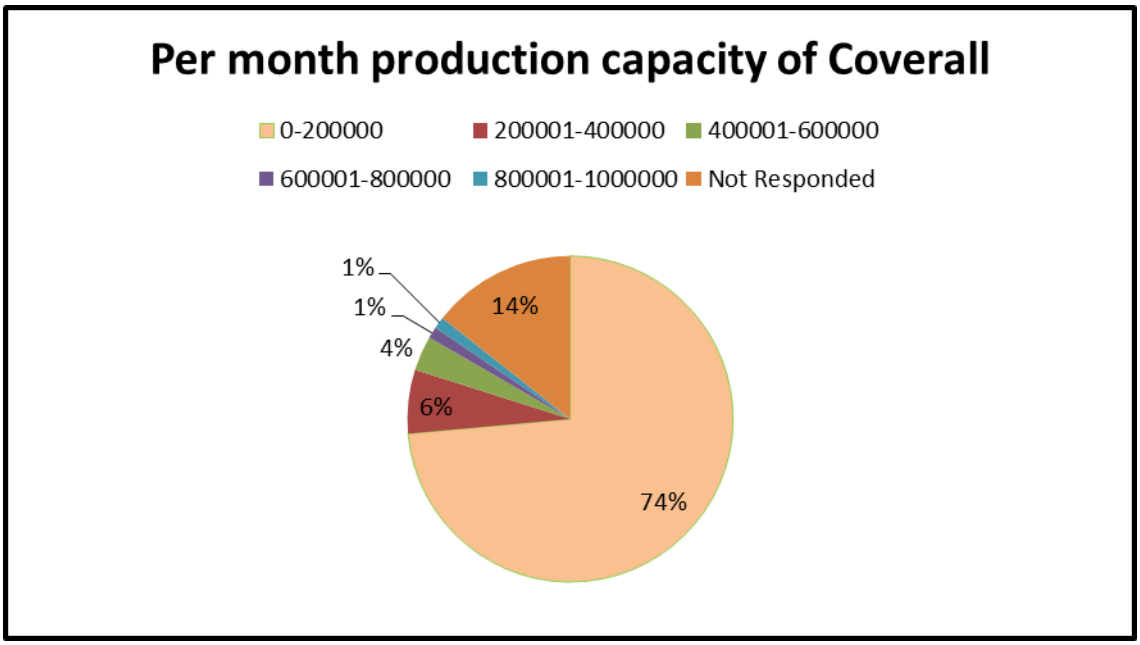

Fig.7

As per Fig. 7,

I. 74% of the respondents have indicated that their production capacity of coverall falls between the range of 0-2lacs.

II. 6% of the respondents have indicated that their production capacity of coverall falls between the range more than 2lacs-4lacs.

III. 4% of the respondents have indicated that their production capacity of coverall falls between the range more than 4 lacs-6 lacs.

IV. 1% of the respondents have indicated that their production capacity of coverall falls between the range more than 6 lacs-8 lacs.

V. 1% of the respondents have indicated that their production capacity of coverall falls between the range more than 8 lacs-10 lacs.

VI. 14% of the respondents did not responded.

8. **What is your production capacity per month of Goggles?(In pieces)**

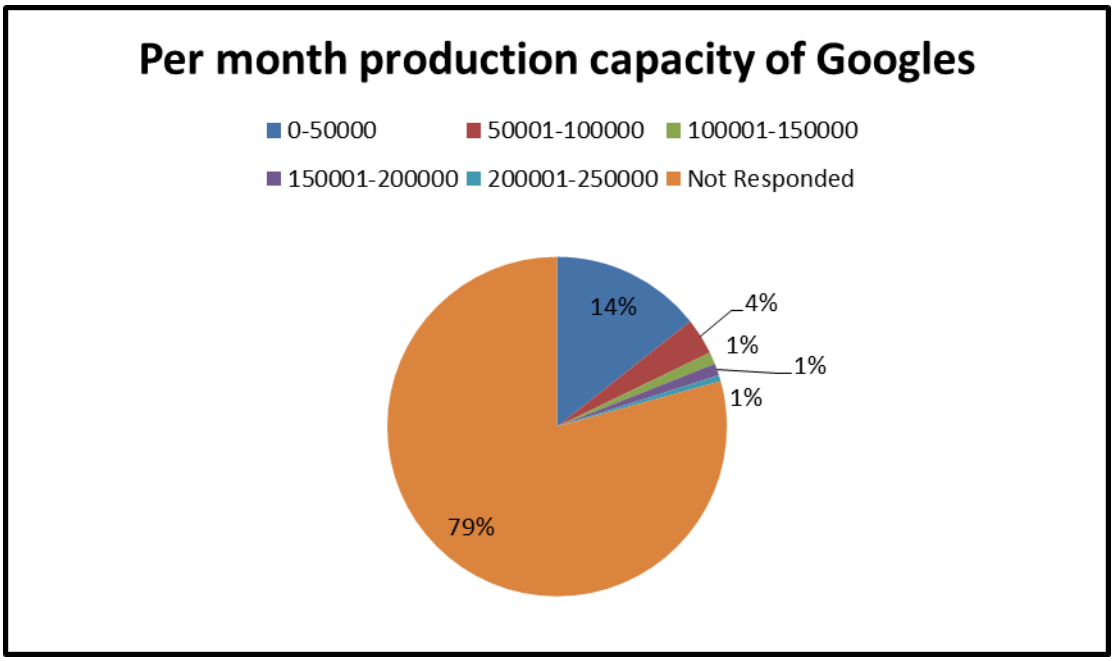

Fig. 8

As per Fig. 8,

I. 14% of the respondents have indicated that their production capacity of goggles falls between the range of 0-5lacs.

II. 4% of the respondents have indicated that their production capacity of goggles falls between the range of more than 5lacs-10lacs.

III. 1% of the respondents have indicated that their production capacity of goggles falls between the range of more than 10lacs-15lacs.

IV. 1% of the respondents have indicated that their production capacity of goggles falls between the range of more than 15lacs-20lacs.

V. 1% of the respondents have indicated that their production capacity of goggles falls between the range of more than 20lacs-25lacs.

VI. 79% of the respondents did not responded.

9. What is your production capacity per month of Face shield/helmets?(In pieces)

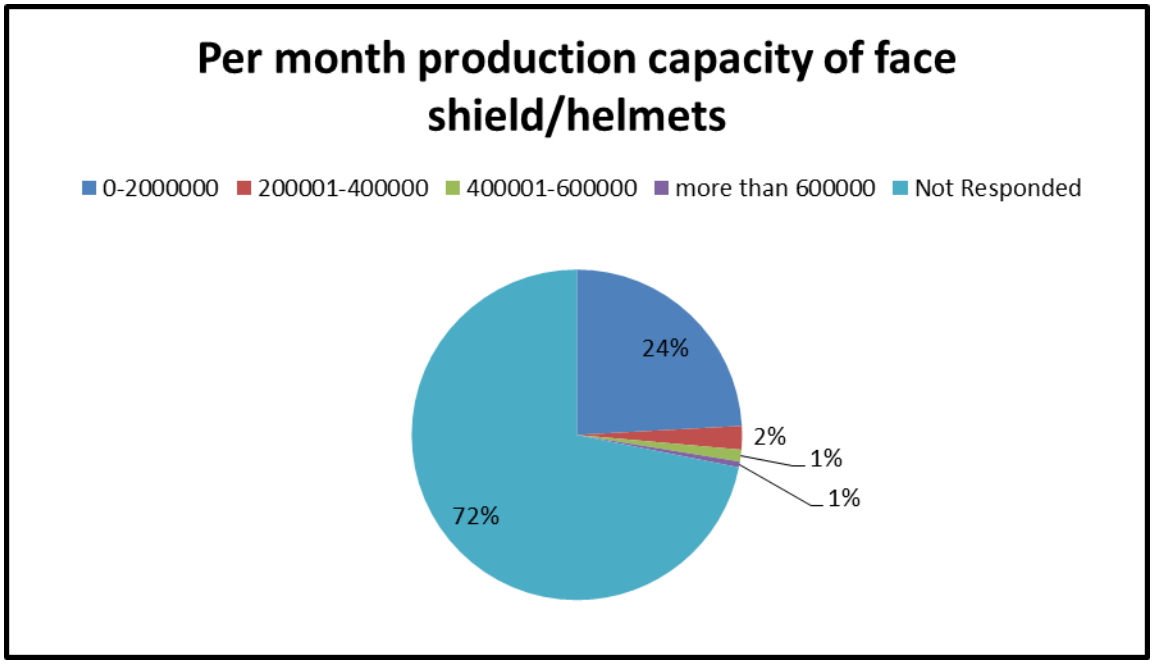

Fig.9

As per Fig. 9,

I. 24% of the respondents have indicated that their production capacity of face shield/helmets between the range of 0-20lacs.
II. 2% of the respondents have indicated that their production capacity of face shield/helmets between the range of more than 20lacs-40lacs.
III. 1% of the respondents have indicated that their production capacity of face shield/helmets between the range of more than 40lacs-60lacs.
IV. 1% of the respondents have indicated that their production capacity of face shield/helmets between the range of more than 60lacs.
V. 72% of the respondents did not responded.

10. What is your production capacity per month of masks?(In pieces)

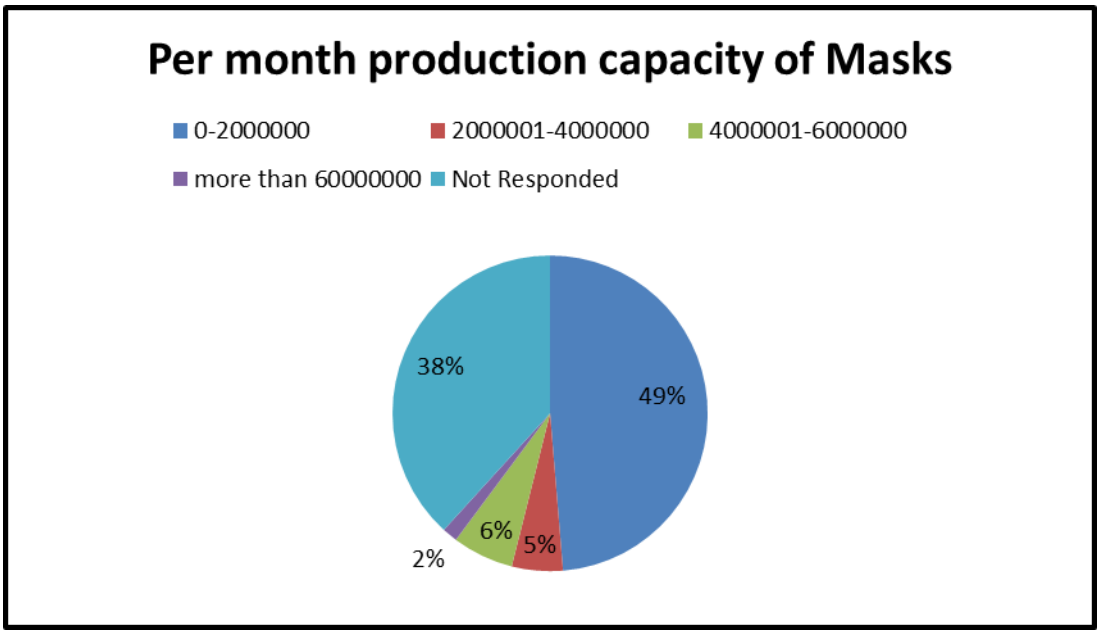

Fig.10

As per Fig. 10,

I. 49% of the respondents have indicated that their production capacity of masks between the range of 0-20lacs.
II. 5% of the respondents have indicated that their production capacity of masks between the range of more than 20-40lacs.
III. 6% of the respondents have indicated that their production capacity of masks between the range of more than 40-60lacs.
IV. 2% of the respondents have indicated that their production capacity of masks between the range of more than 60lacs.
V. 38% of the respondents did not responded.

11. What is your production capacity per month of gloves? (In pieces)

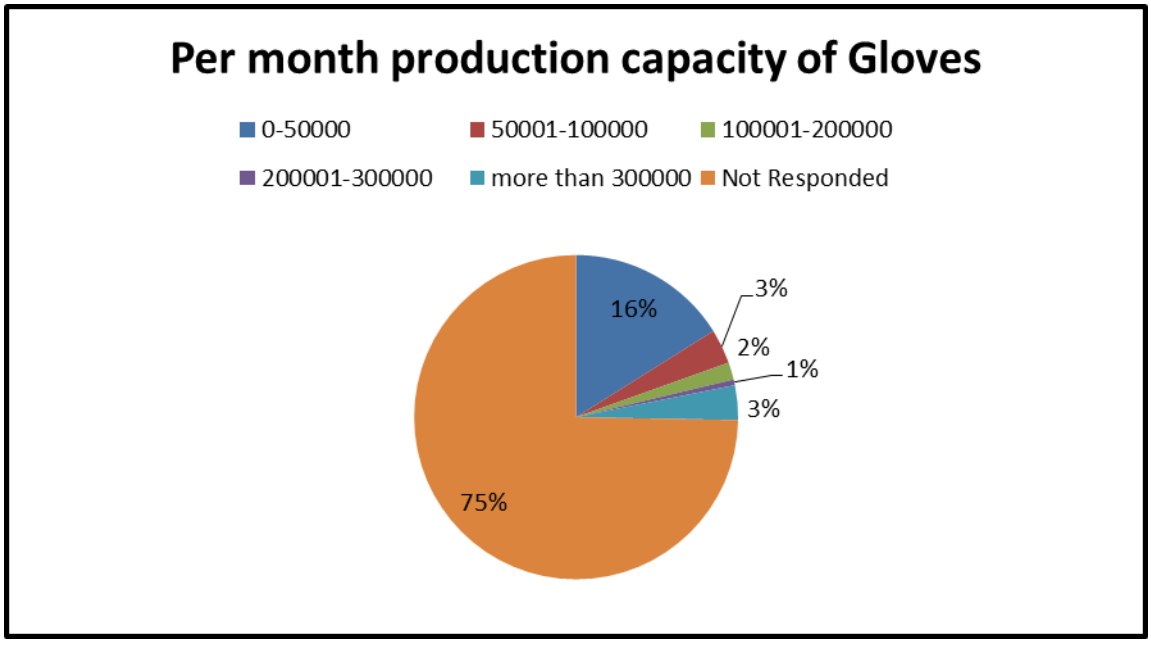

Fig.11

As per Fig. 11,

I. 16% of the respondents have indicated that their production capacity of gloves between the range of 0-50000.
II. 3% of the respondents have indicated that their production capacity of gloves between the range of more than 50000-1lac.
III. 2% of the respondents have indicated that their production capacity of gloves between the range of more than 1lac-2lac.
IV. 1% of the respondents have indicated that their production capacity of gloves between the range of more than 2lac-3lac.
V. 1% of the respondents have indicated that their production capacity of gloves between the range of more than 3lac.
VI. 75% of the respondents did not responded.

12. What is your production capacity per month of shoe cover? (In pieces)

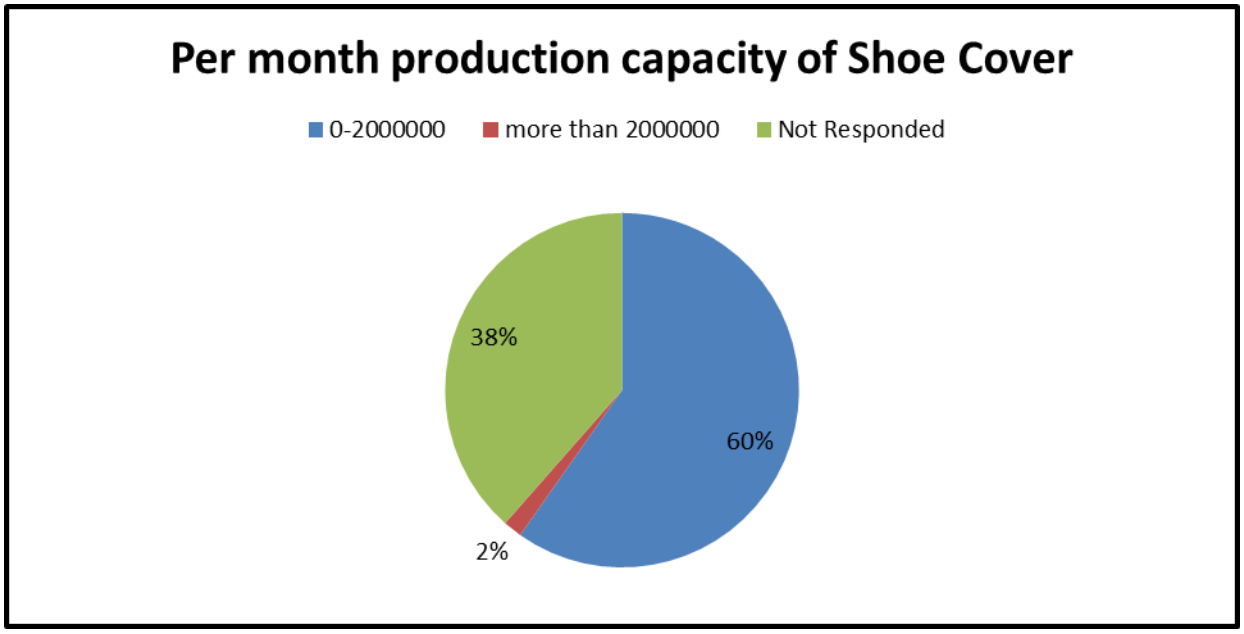

Fig. 12

As per Fig. 12,

I. 60% of the respondents have indicated that their production capacity of shoe cover between the range of 0-20lac.
II. 2% of the respondents have indicated that their production capacity of shoe cover between the range of more than 20lac.
III. 38% of the respondents did not responded.

13. **What is your production capacity per month of Total PPE kits? (In pieces)**

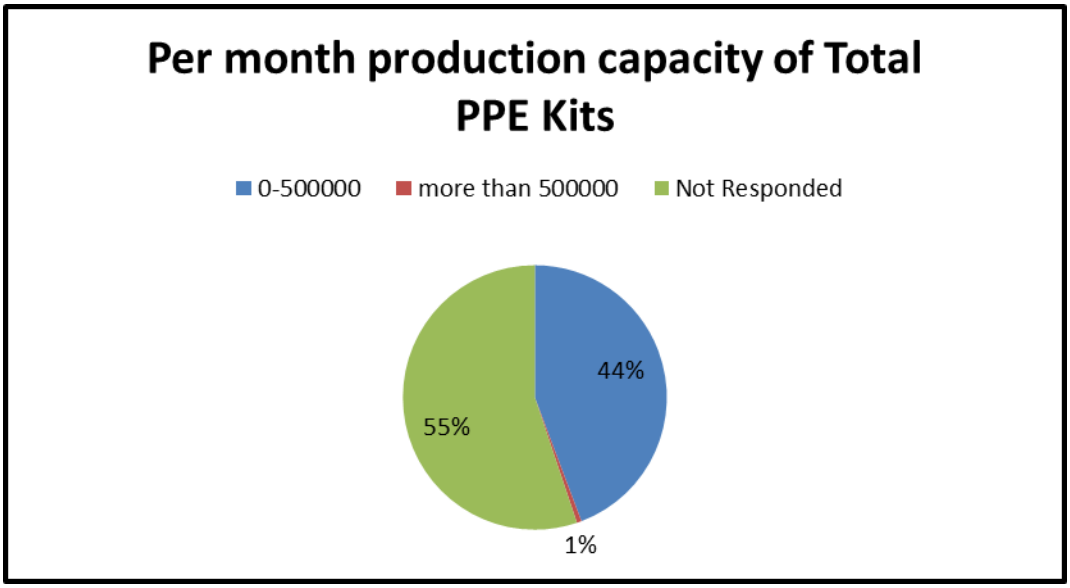

Fig. 13

As per Fig. 13,

I. 44% of the respondents have indicated that their production capacity of total PPE kits between the range of 0-5lac.
II. 1% of the respondents have indicated that their production capacity of total PPE kits between the range of more than 5lac.
III. 55% of the respondents did not responded.

Findings

i. It has been found that the manufacturers who are not currently manufacturing the PPE kits are planning to diversify and getting ready to manufacture the PPE kits.
ii. 88% of the manufacturers who are not manufacturing the PPE kits are planning to start the manufacturing of PPE kits within next two months.
iii. 67% of the manufacturers are planning the capacity of manufacturing PPE upto 1 lakh pieces per month.
iv. From the PPE kits, majority of the manufacturers are already manufacturing coverall.
v. 87% of the manufacturers are manufacturing PPE kits as per WHO specifications.

vi. Majority of the manufacturers are supplying to both domestic and exports market.
vii. Majority of the manufacturer's capacity to manufacture coverall is upto 2 lakh pieces.
viii. 44% of the manufacturers have indicated that their total capacity to manufacture PPE kits is upto 5 lakh pieces per month.

Demand base in India

Many of the respondents have indicated that the major requirement of PPEs are being received from the following :

i. State governments
ii. Hospitals
iii. Military
iv. Indian Railways

Conclusion

In the last two months (March – April 2020), there has been an increase in the diversification and expansion of capacity for production of PPEs. This can be as a response to the demand generated – both domestically and globally. Majority of the manufacturers are already producing or plan to produce the entire PPE kits.

The Council is of the view that PPE exports can be one of the biggest opportunities for India in the coming months and hence the exports for PPE products should be opened up, in case the capacities are adequate to meet domestic demand.

On the supply side, the major constraint is of the machines and inputs required for the production. Both are largely imported at the moment and policy support and capacity building would be imported to increase supplies of these in the coming months. The constraints being faced by the manufacturers of PPEs are non-availability of raw materials, access to manpower and movement of products and services.

An important element of the PPE market is the technical specifications, standards and certifications required. Although the present surge in demand has diluted these requirements to some extent and a large

part of the requirement in the “non medical” category, requiring less stringent norms, going forward, the industry has to benchmark its quality standards to the best. Strengthening the supply chain, with input suppliers like fabric, tapes and other accessories also following the required standards, would be critical for the PPE suppliers to meet the technical requirements. Proper guidelines and compliance support for the whole value chain would be critical in strengthening the PPE manufacturing base in India.

Annex I

Policy Environment-

1. In view of the situation caused due COVID-19, the following products have been banned for export.

S. No.	ITC HS Code	Description	Present Policy
207A	392690 621790 630790 901890 9020	All Personal Protection Equipments including Clothing and Masks [Coveralls (Class 2/3/4) and N-95 Masks].Also includes Surgical Masks/Disposable Masks (2/3 Ply Masks).	Prohibited
207B	9018	All Ventilators	Prohibited
207C	560311 560312 560313 560314 560391 560392 560393 560394	Textile raw material for masks and coveralls	

2. **Exemption from Customs Duty on ventilators, personal protection equipment's, covid-19 testing kits and inputs.**

Exemption to the goods of the description specified in the table below falling within the Chapter from whole of the duty of customs leviable thereon under the First Schedule to the said Customs Tariff Act and the whole of health cess leviable thereon under section 141 the said of Finance Act, 2020 vide Notification No. 20/2020– Customs dated 9th April, 2020. This notification shall remain in force upto and inclusive of the 30th September, 2020.

S.No	Chapter or Heading or sub–heading or tariff item	Description of goods

1	9018 or 9019	Artificial respiration or other therapeutic respiration apparatus (Ventilators)
2	63 or any chapter	Face masks and surgical Masks
3	62 or any chapter	Personal protection equipment (PPE)
4	30, 38 or any chapter	Covid-19 testing kits
5	Any Chapter	Inputs for manufacture of items at S. Nos. 1 to 4 above,subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.

Link to the notification- https://www.cbic.gov.in/htdocs-cbec/legalaffairs/dla_idx

3. State level facilitations

Tamil Nadu has sanctioned a Special Incentive Package to promote the manufacturing of COVID-19 related medical equipment's and drugs including N-95 Masks and PPE kits. The package will be a combination of financial incentives and ease of starting business related facilitations vide Order no. G. O (Ms) No. 113 dated 2nd April, 2020.

(Source-https://invest-india-revamp-static-files.s3.ap-south-1.amazonaws.com/s3fs-public/2020-04/Tamil%20Nadu.pdf)

Annex 2

List of Standards accepted worldwide:

ISO Standards:

- ISO 374-5:2016, Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risk
- ISO 10651-3:1997, Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators
- ISO 10651-4:2002, Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators
- ISO 10651-5:2006, Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators
- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 13485:2016, Medical devices — Quality management systems - Requirements for regulatory purposes
- ISO 13688:2013, Protective clothing – General requirements
- ISO 17510:2015, Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
- ISO 18082:2014, Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases [Including ISO 18082:2014/AMD 1:2017, AMENDMENT 1]
- ISO 18562-1:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic compounds (VOCs)
- ISO 18562-4:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate
- ISO 19223:2019, Lung ventilators and related equipment — Vocabulary and semantics
- ISO 20395:2019, Biotechnology — Requirements for evaluating the performance of quantification methods for nucleic acid target sequences — qPCR and dPCR
- ISO 22301:2019, Security and resilience – Business continuity management systems – Requirements
- ISO 22395:2018, Security and resilience – Community resilience – Guidelines for supporting vulnerable persons in an emergency
- ISO 22320:2018, Security and resilience – Emergency management – Guidelines for incident management
- ISO 22316:2017, Security and resilience – Organizational resilience – Principles and attributes
- ISO 31000:2018, Risk management – Guidelines
- ISO 5356-1:2015, Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets
- ISO 80601-2-12:2020, Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- ISO 80601-2-13:2011, Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation [Including: ISO 80601-2-13:2011/Amd.1:2015, AMENDMENT 1 and ISO 80601-2-13:2011/Amd.2:2018, AMENDMENT 2]

- ISO 80601-2-70:2015, Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
- ISO 80601-2-74:2017, Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- ISO 80601-2-79:2018, Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
- ISO 80601-2-80:2018, Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
- ISO/TS 16976-8:2013, Respiratory protective devices — Human factors — Part 8: Ergonomic factors

Standards provided by IEC:

 IEC 60601-1:2005+AMD1:2012 CSV, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

 IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

 IEC 60601-1-6:2010+AMD1:2013 CSV, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

 IEC 60601-1-8:2006+AMD1:2012 CSV, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

 IEC 60601-1-11:2015, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Annex 3

List of notified bodies are at

- USA – FDA
- Australia Department of Health and Ageing **(MRA)**
- Australia Joint Accreditation System of Australia and New Zealand (JASANZ) **(MRA)**
- Belgium Agence Fédérale des Médicaments et des Produits de Santé (AFMPS) - Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (FAGG)
- Canada Department of Innovation, Science and Economic Development Canada
- Canada Standards Council of Canada
- Croatia Ministry of Health
- Estonia Consumer Protection and Technical Regulatory Authority Estonia Health Board
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- Finland Ministry of Social Affairs and Health - Department for Occupational Safety and Health

- France ANSM : Agence Nationale de Sécurité du Médicament et des produits de santé - Direction de l'Inspection

Annex 4

List of such certifying bodies :

Austria	AKKREDITIERUNG AUSTRIA
Belgium	BELAC
Bulgaria	BAS
Canada	Standards Council of Canada
Croatia	HAA Croatian Accreditation Agency
Cyprus	CYS-CYSAB (Cyprus Organization for the Promotion of Quality)
Czech Republic	CAI (Czech Accreditation Institute)
Denmark	DANAK
Estonia	EAK
Finland	FINAS Finnish Accreditation Service
France	COFRAC (Comité français d'accréditation)
Germany	DAkkS (Deutsche Akkreditierungsstelle GmbH)
Greece	ESYD
Hungary	NAH
Ireland	Irish National Accreditation Board
Italy	ACCREDIA
Latvia	Latvian National Accreditation Bureau (LATAK) State Agency
Lithuania	National Accreditation Bureau
Luxembourg	OLAS
Malta	National Accreditation Board (NAB-Malta)
Netherlands	RVA (RvA)
Norway	NA (Norsk Akkreditering)
Poland	PCA (Polish Centre for Accreditation)
Portugal	IPAC (Instituto Português de Acreditação, I.P.)
Romania	RENAR
Slovakia	SNAS (Slovak National Accreditation Service)
Slovenia	SA (Slovenian Accreditation (Slovenska akreditacija))
Spain	ENAC
Sweden	SWEDAC
Switzerland	SAS **(MRA)**
Turkey	TURKAK (Turkish Accreditation Agency)
United Kingdom	UKAS