Face masks

The role of legislation and standards in mainstreaming reusable options

Brussels, December 2021
Summary

Personal protective equipment (PPE) plays a critical role in the battle against COVID-19, with some types of PPE becoming everyday items. As a result, the growing mountain of disposable PPE is creating a whole new set of problems.

To address the environmental and health impact of this new pollution stream, we need to reduce the volume of unnecessary single-use PPE and tackle face masks composition, all this while reinforcing and guaranteeing mask conformity. Moving away from a mentality of single-use and stockpiling, reusable options can ensure safety while cutting tonnes of waste. In this document, we provide a list of policy and standardisation must-haves to move towards more sustainable and reusable options.

Introduction

In July 2021, the EU waved goodbye to the most common single-use plastics items. However, an essential one was left out of the ban: disposable face masks1.

Personal protective equipment (PPE) and face masks play a critical role in the battle against COVID-19 and have become everyday items worldwide. As a result, a growing mountain of disposable PPE is creating a whole new set of problems1 while the plastic waste wave continues to rise.

Littering of those products is visible everywhere. Not only that, they are often discarded in mixed municipal solid waste. When those products break down in the environment, they cause microplastic pollution1.

To tackle this problem, it is essential to:

- rethink our dependency on single-use items,
- address the environmental and health impacts of this new pollution stream,
- move away from a mentality of single-use and ‘stockpiling’,
- work towards more sustainable, reusable, effective and long-lasting solutions.

Reusable options2 can ensure safety3 and steady supply while cutting tonnes of waste and greenhouse gas emissions, contributing to the EU’s climate policy goals.

The EU response to the COVID-19 crisis needs to take a more strategic, forward-looking approach, considering the health and environmental implications of this waste stream. To do so, sustainability and material efficiency aspects must be included in PPE-related legislation and standardisation. In this document, we provide a list of policy and standardisation must-haves to move towards more sustainable options, allowing for reusability.

4 A history of the medical mask and the rise of throwaway culture. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31207-1/fulltext
**Tackling volume, composition, and conformity**

*Reduce the unnecessary use of single-use PPE and face masks*

Both the sheer volume of disposable face masks and their composition raise environmental issues. To stop this mountain of disposable PPE and face masks, we need an ambitious policy framework that boosts reusable options and brings sustainability to this sector. It is important to stress that standards and certification for those products so far focus on requirements for safety, health functions and conformity with the relevant legislation (Regulation 2016/425). However, they do not include any considerations for circularity, nor do they include any guidance on reuse and repair. Product requirements related to durability, longevity, reuse, reprocessing, repairability and recyclability need to be integrated into European policies and supported by appropriate assessment methods.

Imports of face masks into the EU more than doubled as compared to the pre-pandemic situation. EU production also increased. Between April and September 2020, the EU imported 170,000 additional tonnes of face masks and 105,000 more tonnes of gloves as compared to 'business as usual'. Greenhouse gas emissions related to the manufacture, transport and waste treatment of single-use face masks range from 14 to 33.5 tonnes of carbon dioxide equivalent (CO₂e) per tonne of masks, corresponding to greenhouse gas emissions of 38-90g CO₂e per face mask. As a comparison, a pack of 100 masks represent approximately a 33-74 km trip by car in the EU.

These numbers need to be dramatically cut through long-lasting solutions. For example, a reusable cotton mask used thirteen times has a lower impact than using as many single-use masks.

We need policies to:

- Promote reusable options, as they ensure safety while cutting tonnes of waste. In particular, public procurements for those products should favour reusable options and product-as-a-service solutions. This should be achieved by 2023, with the development of harmonised GPP criteria for PPE or PPE specific reference, as foreseen in the JRC Report *Revision of the EU Green Public Procurement (GPP) Criteria for Textile Products and Services*. GPP enhances environmental technologies’ innovation, serves as a levy and an example for private procurement.

- Define criteria, requirements, and methods for those products’ longevity, durability, reuse, reprocessing, repairability and recyclability. These should be tested and vetted in order to ensure health and environmental safety. PPE and General Product Safety (GPSD) legislation should be revised by 2023, with a view to integrate sustainability and material efficiency objectives, requirements, ecodesign principles, and make these elements a key selection factor in public procurement. Standards should support the development of suitable test methods.

- Provide information to users about the reuse system in place and its functioning, including clear instructions and methodology for sustainable disposal once the product has reached the end of its lifespan.

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5 Average g CO₂/km emission of a new registered vehicle (122.3 g CO₂/km) [https://www.eea.europa.eu/ims/co2-performance-of-new-passenger](https://www.eea.europa.eu/ims/co2-performance-of-new-passenger)
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- Minimise exposure to chemicals of concern – including the full disclosure and traceability of chemical substances used, with clear labelling. Move to safe and sustainable-by-design chemicals and support R&D seeking to find safe alternatives to substances of concern.

Those policies should be supported by standards that would:
- Define a shared method for reprocessing, washing, sterilised reuse processes and handling safety protocols, preventing contamination and ensuring safety against health and environmental risks.
- Establish test methods for verifying product durability through multiple reuses, ensuring health and environmental safety.
- Include product specifications for longevity, durability, and recyclability.
- Specify criteria for harmonised reuse infrastructure and for process requirements in order to collect, transport, wash, reprocess and reuse.

These policies would lever a scale-up of reuse systems and enable system efficiencies, supporting a change toward circular economy in this sector, while leading to significant cost reductions for healthcare professionals\(^9\)\(^10\).

**Tackle face masks composition**

Many face masks end up as potentially toxic micro- and nanoplastics or carriers for other toxicants in the environment, researchers warn\(^12\). They are likely to accumulate and release harmful chemical and biological substances, such as bisphenol A, heavy metals, PFAS, flame-retardant and biocidal substances posing adverse impacts on plants, animals and humans. Besides the clear environmental impact, there are also many health concerns: a study found potentially dangerous chemical pollutants including lead, antimony, and copper, released from disposable face masks\(^13\). A second one found that most surgical masks analysed contained titanium dioxide (TiO2), classified as possibly carcinogenic when inhaled by IARC\(^14\)\(^15\), in quantities ranging from 100 ppm to 2000 ppm. The European Commission proposed to ban titanium dioxide in food from mid-2022 after the EU’s food safety agency’s opinion on its safety\(^16\).

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8 https://www.eu-esf.org/covid-19/4647-covid-19-is-a-mask-a-mask
9 Currently being reviewed.
10 https://cleanmedeurope.org/wp-content/uploads/2021/03/Alexis-Percival_Reusable-facemasks-Greener-NHS.pdf
11 https://www.nutraingredients.com/Article/2021/11/08/Titanium-Dioxide-ban-on-schedule-for-Jan-2022-as-Member-States-vote-in-

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**Face masks – clarification box**

There are different types of masks (protective, medical, community face masks…)\(^8\)\(^9\) with different legal requirements depending on the function of the mask:
- **Protective masks** – PPE regulation, with CE marking – EN 149,
- **Medical masks** – Medical Devices Regulation, with CE marking – EN 14683,
- **Community face masks** – Regulated mostly through GSPD, without CE marking – CWA 17553\(^9\).

To clarify: community face masks reduce the projection of the wearer’s respiratory saliva droplets or respiratory secretions. They might also reduce penetration of respiratory droplets from an external source, without claiming protection for the wearer. In short, community face masks protect others from the user, less so the other way around.
PPE and GSPD laws need to be revised to:

- Include dedicated requirements for composition, materials and chemical use, ideally excluding some based on health and environmental risks and effects.
- Include an assessment to further determine if a products’ functionality and performance justify the continuation of the use of hazardous chemicals.
- Withdraw the exemptions for substances of very high concern in medical textile products: not all products need PFAS, heavy metals, nor flame retardant, depending on the function. These chemical applications should be restricted to essential-use only. The extent of the problem was that the European Commission issued guidelines to provide basic indications and alternatives should be explored and supported.
- Hazardous chemicals need to be phased out where possible. Where not feasible due to requirements and use of the products, safer alternatives should be prioritised. These do not necessarily imply having the same performance at a higher price.

The Chemical Strategy for Sustainability has a crucial role in increasing investment and innovative capacity to provide safe and sustainable chemicals, which is important to offer solutions and support the green transitions of both our economy and society\(^{17}\).

**Conformity needs to be reinforced and ensured**

During the pandemic, an issue widely reported was the lack or limited control over conformity with standards and quality of disposable PPEs and face masks. The extent of the problem was so significant that the European Commission issued guidelines providing basic indications to identify whether a product was lawfully placed on the EU market, calling on the public to watch out for misleading or falsified documents and counterfeit products\(^{18}\). Conformity assessment of PPE, face masks (and their declaration), alongside the presence of CE marking, have also been reported to be used in a non-appropriate manner, with many instances of fraud\(^{19}\).

Hence, market surveillance needs to be strengthened with a series of actions:

- Withdraw the Recommendation (EU) 2020/403 on conformity assessment and market surveillance, which allows EU member states to be flexible for products relevant to the crisis. The 'urgency' approach should give way to a long-term vision.
- Dissuasive penalties should be introduced for non-compliance.
- Cases of non-compliance need to be publicised by communicating the brand name of the non-compliant models.
- The European Commission should perform its own independent market surveillance and make proposals on how to further improve surveillance mechanisms.

To conclude, it is time for sustainable products to be the norm, including PPE and face masks.

Supported by:

17 https://ec.europa.eu/environment/strategy/chemicals-strategy_en
18 https://ec.europa.eu/docsroom/documents/41385