

PANDEMIC REFLECTIONS

*A review following the PPE crisis
of 2020*

The British Safety Industry Federation (BSIF) is the UK Trade Association for the Safety Industry, whose members include the manufacturers, importers, distributors and specialist service providers in personal protective equipment (PPE) and associated safety apparatus

BSIF was established in 1994 and since that time has been providing leadership and authoritative information on a wide range of workplace safety issues and representing the needs of the UK market and the country's work force. It is our mission to support all businesses in the UK who help to keep people safe and healthy at work and we are passionate that safety and health is universally recognised for what it is – a positive force for good.

BSIF works closely with the Health and Safety Executive and Trading Standards with whom we have Primary Authority partnership. BSIF are the UK's leading association for the Personal Protective Equipment (PPE) Regulation 2016/425 and provide guidance for PPE compliance, working closely with Regulators and are active across a range of Government departments.

Executive Summary

This document was written during the latter stages of 2021, after some of the dust had settled around the PPE crisis created by the Covid-19 pandemic. The events of 2020 elevated the profile of PPE to a level never seen before and highlighted the dependence the country has on extended supply chains.

The pervasive marketing of non-compliant and unsafe PPE, on a grand scale, shone a very bright light on the lack of regulatory control for these safety critical products and resulted in the market being full of potentially unsafe product. The existence of poor quality PPE, while extreme during the pandemic, is not a phenomenon just of that period. These concerns and the vulnerabilities that result were already known to BSIF and those of the industry.

Pandemics may re-occur and when they do, the country must not be in a position where unsafe PPE is prevalent.

While this document sets out to review and reflect on the events of 2020 and BSIF's efforts to support the country's response, it calls on action now to be address the current and ongoing marketing of PPE which is non-compliant and not fit for purpose.

This paper calls upon the authorities to take 5 simple steps to enforce Regulation and ensure that users get the protection they need from their PPE. The actions are laid out at the end of this paper however, in summary this review states that....

We call upon Trading Standards to take immediate action on existing reports we have already made.

We call for the penalties to reflect the seriousness of illegal PPE selling, putting users in danger.

We require the authorities to act if PPE is not compliant with existing Regulation and therefore not proven to be safe, without the burden of further testing to prove that it is "unsafe".

We call on the legislators to act against the avoidance of responsibilities by on-line selling organisations spreading the sale of non-compliant PPE with apparent impunity.

We further call for operative in-market enforcement to be the responsibility of only one agency, not two as we currently have.

The landscape

The Covid-19 pandemic began around December 2019 in Wuhan, China and had reached Europe by early 2020. Wuhan, as it happens has historically been a manufacturing centre for limited life PPE including respiratory protective equipment, protective suits and other relevant items such as medical masks.

Many PPE items, while safety critical, are high volume but relatively low unit value, and much of their manufacturing has long been off-shored to China.

By late February of 2020 BSIF began hearing of interruptions in PPE supply and reports of the Chinese Government taking control of PPE manufacturing and directing product exclusively for domestic use.

At that time BSIF advised the Health and Safety Executive (HSE) of likely shortages. Our alert to the HSE was driven by concerns that PPE stocks for the industrial safety and health market would be significantly affected, but given the incredible scale of what very quickly unfolded, this concern for the industrial market, in hindsight, seems almost parochial and even naïve.

Some short weeks later with Italy in lockdown and their health service overwhelmed, the demand for Covid-19 related PPE exploded, first across Europe and then globally. This we must remember was at the same point that the authentic supply chain was collapsing, a perfect storm of skyrocketing demand coupled with dwindling resource. By the start of March BSIF was supporting the UK authorities who were scouring for immediate supplies of FFP masks for front-line healthcare staff.



We all now know of the alleged cronyism and the legally questionable VIP/Fast Track for those allegedly with political connections, along with the amount of money spent on “PPE”, (National Audit Office estimate £15 billion) often with suppliers who had no knowledge or expertise in this market. However, for the purposes of this piece I do not intend to dwell on this strategy.

By the beginning of March 2020 BSIF were providing constant support and information on PPE sources to the Cabinet Office, the Crown Commercial Agencies and the various structures supporting the NHS and the public health agencies across the devolved nations. We supplied all the senior contact information for legitimate manufacturers and suppliers in the UK and across Europe, in order that the authorities could communicate directly with the right people. In addition, along with the European Safety Federation (ESF) we did the same for the EU Commission who were seeking to source communally, on behalf of member states. While this was happening the UK’s strategic pandemic PPE stocks were being audited and very often found to be beyond their useful life.

This crisis was well and truly upon us.

In response to the shortages certain EU states unilaterally prohibited the export and free movement of PPE with ranges of conditions applied by the various member states. The ensuing chaos of this action led to the EU publishing “Recommendation 2020/402” which required any exporting of PPE to undergo an “authorisation” process.

BSIF and ESF were very active in engaging with the Commission and other authorities on the damage that such a poorly designed protectionist process would do. In the first place PPE and Covid related PPE do not have identifiable tariff codes and furthermore many international PPE manufacturers who warehoused centrally in EU states, including the UK, had difficulties moving product to legitimate priority markets.

The pandemic and this recommendation was creating unhelpful reactive protectionism which was not helping supply. In the UK Her Majesty’s Revenue and Customs (HMRC) took the lead in providing approvals for the movement of relevant products. BSIF liaised closely with them at this time.

There was a growing media outcry as the essential services clearly did not have enough PPE and often what PPE they had was not of the appropriate quality.

Subsequently the EU Commission produced their “Recommendation (2020/403) on allowing PPE for covid facing healthcare workers, to be placed on the market without it having to go through the full product approval processes. A clear sign of how desperate the supply situation had become. Once again, along with ESF, we challenged the EU Commission on potential dangers of this move.

In parallel BSIF began to work extremely closely with the Department of Business Energy and Industrial Strategy (BEIS) and the Office for Product Safety and Standards (OPSS) on supporting how the EU Recommendation 2020/403 could be employed in the UK.

We proposed a triage system of receipt and testing of PPE, recommending appropriate laboratories with easy access to and from Heathrow (the original planned port of arrival for PPE). In the end a version of the proposed system was set up, led by a dedicated OPSS/HSE technical team working out of the MoD facility in Daventry. This team were charged with “accepting and releasing, fit for purpose PPE” sourced directly by the Government on behalf of healthcare workers.

By April 2020, and with the active participation of BSIF, BEIS/OPSS produced the first Guidance on how Recommendation 2020/403 could be applied in the UK. The “Recommendation” changed the process by which PPE would be allowed to be placed on the UK market. Along with the consultations we provided to BEIS/OPSS on creating the Recommendation Guidance, once published, it had to be interpreted and communicated to the BSIF membership and the wider market including end users.

The first “Guidance” produced in April 2020 was followed by many subsequent revisions as the circumstances developed. By September 2020 some 15 iterations of the Recommendation Guidance had been published and as each update was produced BSIF reviewed and cascaded the information to the stakeholders and the market. Recommendation 2020/403 was to be applied by member states (including the UK) as they each saw appropriate for their own specific needs. Confusion, over what the “Recommendation” actually allowed and how it should be applied, was significant with the member states and Notified Bodies giving “approval decisions” as they saw fit.



The government, in parallel had put out the call for UK based manufacturers to convert production to Covid-PPE and many did. Once again however, we had many businesses, well-intentioned, but lacking in the appropriate knowledge making PPE and attempting to have it certified under the temporary easement. The results were very mixed. At this time the BSIF Test and Certification Association, the group of UK Notified Bodies, were constantly meeting (remotely) and debating the actions necessary to apply the Recommendation consistently in the UK. This unique collaboration

provided for the Government through the BSIF Test and Certification group, was extremely valuable to BEIS/OPSS, even if ultimately the process was imperfect.

Coinciding with the soaring demand and fracturing of traditional supply chains came an eruption of other opportunist businesses attempting to supply PPE into the UK. It appeared that anyone with international trade connections in any product category was now supplying PPE. They were doing this without understanding the critical nature of the product and with little attention paid to compliance or product provenance. Internet portals and online marketplaces were promoting significant quantities of non conforming unproven PPE. It was not just the traditional online platforms selling these products, they were also being sold in increasing numbers by individuals on their personal Twitter and LinkedIn accounts, and at hugely inflated prices. Once again, when alerted, BSIF staff would engage and encourage these sellers to desist. This engagement with individuals was often a fraught and unpleasant experience.

The authorities appeared unwilling or unable to stem this tide. Note, that while we use the term “PPE” within this text, the priority focus early on, was around the supply of filtering facepiece FFPs (disposable masks). However, as the months of the crisis wore on, the supply of other PPE items such as face shields, limited life garments and gloves were also added to the list of products in short supply and subject to the same abuses as were experienced with respiratory protective equipment. End users, the vast majority in healthcare and essential services, were absolutely desperate to find supply, but very often did not know what legitimate product looked like. The BSIF staff, mostly working remotely since the end of March, were completely occupied and utterly absorbed in supporting members, non-members, end users and the authorities, constantly reacting to their PPE questions.

BSIF were asked to contribute to the creation of PPE Guidance for GP Surgeries, which of course we were more than happy to do. At this time we began to see the arrival of FFP masks with “ear loops” instead of the “adjustable head harnesses” as required by the product standard. In most cases the FFPs being supplied were “KN95” a classification of respirator under the Chinese domestic standard GB2626. The KN95 is not compliant with the UK or European PPE standards. Many of the products were not even legitimate KN95 certified respirators. Yet despite it clearly being outside of the Regulation the products were flooding the market. In April 2020 a UK Google search for KN95 resulted in some 16 million hits. The ubiquitous KN95 was being commonly marketed as KN95/FFP2, but they are not the same thing, they perform differently with testing and quality assurance requirements less stringent than an FFP2 under PPE Regulation 2016/425. The HSE were aware of the product and its drawbacks and finally in June 2020, after much chasing, the HSE position was clarified via a “Safety Alert”, warning against the use of KN95 to protect against Covid-19. BSIF were asked to contribute to the creation of this “Safety Alert”, which we did. Still the KN95 masks were being sold openly.



As part of BSIF's support work we would engage with all suppliers, and those selling non-compliant products would be advised of their regulatory obligations and helped wherever possible to avoid selling non-compliant unsafe PPE. BSIF's engagement and advice was often unwelcome and the suppliers who did not respond positively, were "eventually" reported to the market surveillance authorities. By the end of 2020 we had made over 350 reports of non-compliant PPE to the authorities. How many of these were prosecuted? There are only 2 in process that I know of.

In addition to the omnipresent KN95 we began to see, for the first time in the UK FFP masks certified to EN149 with ear loops, instead of adjustable head harnesses. Such masks will struggle to "face fit" properly, failing to provide a seal with the face leaving the wearer unprotected. The HSE and the NHS refused to allow the wearing of FFPs which had ear loops for just this reason. At this juncture it is important to appreciate that HSE maintained their insistence on the need for face fitting when any tight fitting respirator such as an FFP was deployed. HSE are to be commended for maintaining this stance. However, the supply of the same make, model and size of the masks was not happening, therefore wearers were required to have multiple face fit tests across a range of masks.

There were insufficient competent face fitters available and the kit necessary for carrying out face fits was also in desperately short supply. At one point BSIF were actively supplying the recipe for the manufacture of the test agent used in the "Qualitative" method to potential manufacturers. However, it must be recognised that Fit2Fit Accredited face fitters performed superbly carrying out over one million face fits in the NHS Trusts and in the new Nightingale facilities in really difficult circumstances. At one point members of the army were also brought in to assist in the coordination of face fitting but that initiative appeared to peter out as quickly as it began. BSIF and the Fit2Fit community attempted to organise, coordinate and prioritise face fitting through the Cabinet Office, which though well intentioned and appropriate, was ultimately not the best way forward. A confused time was certainly not helped by the fact that contacts within the Cabinet Office who we had been supporting were often, not as it turned out Cabinet Office staff, but one of the multitude of Deloitte consultants working for the Government and subject to very quickly moving on to different pandemic response teams.

Many areas of our society were now confronting the need to wear PPE to mitigate against the risk of Covid including GP and Dental Surgeries. Dentists, closed since late March were by June attempting to re-open but needed the appropriate PPE and face fitting for respirators. Once again with little background in PPE, or respiratory protective equipment or the need for face fitting, the situation in dental was utterly chaotic. During 2020 the BSIF office remained manned at all times, and I can honestly tell you that, for a 3 month period we answered a phone call from dental practices once every 5 minutes!

The Royal College of Nursing and the British Medical Association were also concerned and wrote to BSIF, not specifically on product quality but on the challenge of providing respiratory protective equipment suitable for the diverse NHS workforce. BSIF were able to point out that in normal times adequate and suitable masks were indeed available but hitherto not selected or specified by NHS purchasing managers.

Chaotic times, but in support of the market BSIF created a webinar to assist users in identifying safe and compliant PPE. With over 1,200 participants, the webinar reached and provided advice to end users, market surveillance authorities and other potential PPE suppliers. From the webinar, 200 questions were submitted and all were answered by BSIF and posted on the website within 5 days.

To coincide with the webinar we produced and published a series of documents to help users and potential suppliers identify genuine PPE amongst all of the non-compliant and illegal product being offered in the market. We also produced a video-guide to navigating the EU NANDO database in order to help individuals authenticate products and genuine documentation.

BSIF produced and publicised a series of guidance documents including “Is it Genuine” to illustrate what users and inexperienced suppliers should be looking for when checking PPE paperwork. At this time there was also the conflation of medical masks and PPE requiring BSIF staff to develop at least some expertise in Medical Device Regulations, as well as reaching out and creating relationships at the Medicines and Healthcare products Regulatory Agency (MHRA)!

At every turn, non-compliant PPE was being placed on the market and central to the problem was a huge number of bogus, fraudulent, dishonest and misleading documents offered in support of the product. BSIF staff were called upon to verify document after document and certificate after certificate. Some of the paperwork was clearly fictional, some wrong, not what was required by legislation, others misleading and some copies of legitimate paperwork applied to different products.



There was also something of a growing phenomenon whereby several Notified Bodies (not scoped for PPE approvals) were providing certificates purporting to be CE certificates for PPE but which were nothing of the sort.

It was the birth of a very profitable activity selling worthless certificates without authority. Bordering on the criminal this activity just added to the galloping confusion.

Along with fake certificates we also saw the emergence of bogus certification bodies offering CE PPE approval decisions. These supposed providers were utterly fictional swindlers “offering” illegitimate services to the unsuspecting. Where there are shortages you do not have to wait long for the profiteers, the corrupt and the unscrupulous to appear!

BSIF were at all times front and centre in the efforts to keep bad PPE from the market and after following up on market intelligence and feedback, we would investigate and establish validity or otherwise, engaging with those involved and ultimately ending up reporting over 350 instances of wrongdoing to the authorities.

The Federation were supporting the market all the way through and against this background we have to ask the questionIf it had not been for BSIF then who would have provided these vital services?

The challenge going forward is for the country to be prepared for the next time a crisis of this nature occurs. There is an enquiry scheduled in early 2022 on the pandemic response, and we are “promised” it will examine all the circumstances and actions in the handling of the crisis.

However, given the time such enquiries take, we call on the government now, to design and publish a PPE Strategy which will enable the timely provision of adequate and suitable PPE for frontline and emergency services without billions of pounds being wasted and the safety marketplace polluted with non-compliant and potentially dangerous PPE.

This Strategy must create a workable set of contingencies involving the appropriate regulators and experienced PPE manufacturers, along with approval bodies and logistics experts.

As a minimum a task force should be in place including, but not limited to OPSS, BEIS, HSE, MHRA, an empowered representative of Trading Standards and the BSIF. In this way a plan can be ready and on the shelf to provide rapid reaction for PPE security.



So what lessons have we learned?

We learnt that the UK was unprepared for the pandemic and that it appeared the authorities did not understand PPE. Existing stock was woefully inadequate and reactive supply attempts disorganised and chaotic, with much of the stock brought in not fit for purpose.

We learnt that a great deal of non-compliant, unsafe PPE was able to be placed on the UK market with the authorities often apparently incapable of stopping it. This was not news to BSIF, but the exaggerated volumes highlighted the problem with dramatic effect. However, we also learnt that ultimately where there is enough publicity the authorities will take an interest in ensuring that PPE is fit for purpose. A dedicated technical team headed by the HSE triaged incoming shipments of PPE purchased directly by the Government on behalf of the NHS and Healthcare and the HSE also established a Product Safety Market Surveillance Unit and were then actively engaged on PPE market surveillance and intelligence gathering. Many of the HSE team involved at the time have since been re-directed onto other activities.

We learnt that the legislators, the market surveillance authorities and the institutions of this country did not have adequate PPE knowledge but with direction and focus created by the crisis they will seek training and input. BSIF provided access to the content of our **Safe Supply Qualification** modules on Product Standards and Certification. The learning provided by BSIF was used by OPSS and the Chartered Trading Standards Institute (CTSI) to help their field officers. We learnt, or had re-enforced, the ease by which bogus products are sold via the internet, with the market surveillance authorities impotent to stop it. Further the authorities appear content to stand behind the spurious “safe harbour” defence of portals taking no responsibility for the PPE their platforms promote. ***We know this has got to change!***

Ultimately the PPE crisis of 2020 will be seen as a moment in time but the problem of non-conforming PPE continues and will continue until the enforcement of the applicable Regulations are effective. PPE was a significant priority in 2020, a topic central to the political challenge of the time. It no longer is. Will it ever be again without there being a national crisis and indeed is that, as it would appear, what is needed for action by the authorities? The country must be prepared for the next pandemic and in the context of PPE it must have a robust strategy in place.

The tax payer funded in-market, enforcement authorities, which in the case of PPE means HSE and Trading Standards, are responsible for enforcement of the PPE Regulation, but effective enforcement just does not happen. It would be wrong to say that nothing is done by the market surveillance authorities but what is done is not enough and not successful when it comes to keeping bad product off the market. BSIF have a Primary Authority Partnership with Hertfordshire Trading Standards and through that they “lead” on PPE. However, when we channel validated concerns to them Hertfordshire must pass the file on to the relevant Trading Standards office located in the council area where the concern has come from. They have no involvement from that point and cannot direct the specific council trading standards personnel to take action. Further individual councils around the country, for whom each Trading Standards Office works, are short on resource and short on budgets to spend on product testing, something they often need to do to prove a product is non-compliant or unsafe. Here we have another issue, which is that unsafe products are defined by risk assessment of the potential harm that product could do to a wearer or a user, for example, risk of electrocution, risk of causing a fire, risk associated to poisoning or choking. Non-compliant PPE will rarely fall into these definitions but PPE by its very nature is utilised to protect a wearer while exposed to an existing established hazard, and if it fails to perform the wearer will be immediately at risk and un-protected.

BSIF are in discussion with OPSS on redefining the risk assessment of “unsafe” products in the context of PPE and we are arguing that any item of PPE which cannot prove that it will perform should see immediate intervention. It must be remembered that PPE, under Regulation 2016/425, already has both that responsibility and the opportunity to prove safety and performance, through the established approval and certification process. Straightforward enforcement just needs to be undertaken!



There is another worrying trend undermining enforcement and that is that Trading Standards are primarily “encouraged to support” and help a business to be able to comply with their statutory responsibilities, as opposed to taking early enforcement steps. In principle this may look like a sensible proportionate response but it is a long process of some may argue “hand holding” and ensuring corrective actions are undertaken. BSIF argue that “enforcement” is in itself support for the wearers of PPE ensuring safety and, for the already compliant producers it enables fair competition.

If we look at the results of product audits under the Registered Safety Supplier Scheme during 2021, post the “PPE availability emergency”, we see over a wide range of suppliers PPE non-compliance running at a rate of 29% on tests undertaken across the product types. The problem is clear and the problem is present.

The testing and the results illustrated above come from BSIF and are passed to the authorities as appropriate, should it not be the market surveillance authorities who are proactively investigating and producing the findings and then acting on them? Of course it should! But, worse still, in one specific category of PPE a BSIF member (outside of the Registered Safety Supplier Scheme work) has compiled over 60 separate reports on traders selling non-compliant safety clothing, with these details then submitted to the authorities but with no obvious action taken. This is unacceptable.

The PPE Regulation 2016/425 exists to keep wearers safe and to a lesser, but still important, extend helps to maintain a fair and level market place.

The action that we saw the market surveillance structures take, on the narrow range of Covid related PPE was because it was a an unprecedented crisis within a political storm, and we hope that it never happens again, but are we not entitled to see the regulation enforced effectively, day to day? It is, a national disgrace that product safety regulations covering PPE are not enforced as they should be.

However outside of a crisis situation is it perhaps naïve to continue to call on the authorities for action? Let us accept that in a society with finite resources priorities clearly need to be established, and so we have to consider in the round, where enforcement of the PPE Regulation should come on that list?

There appears too few resources to fix health and social care, our police forces appear unable to investigate burglaries and fraud, social-services seem unable to effectively protect children, our border forces and environmental protection agencies are also clearly stretched. So where is enforcement of the PPE legislation in any such list? Perhaps understandably by the very nature of other societal priorities, the answer is a long, long way down, if featuring at all.

So what can be done?

We have already laid out what needs to happen on the strategic pandemic response level, but events of the pandemic highlighted the problem of product compliance we encounter every day in the safety industry. Action must be taken to protect those that rely on PPE in the general market.

PPE is critical to wearer safety and of course goes far wider than the narrow range of covid related PPE. So we insist that the Regulation is enforced and users kept safe in the short term and have their long term health protected. Achieving more resource and a transformation in approach by the authorities seems unlikely to happen, but we believe that some simple actions will produce disproportionately strong results in the battle against unsafe non-compliant PPE being placed on the UK market.



These simple actions must include the following...

1 Trading Standards take immediate action in those examples already supplied to them, even if just a handful. The consequences should be “prosecution” under the existing PPE Regulation and indeed under consumer law. There are sufficient concerns already reported and lodged with the authorities to enable progress.

2 We call for the penalties, while proportionate, to recognise that selling non-compliant PPE is putting wearers in danger and that it is fraudulent. Penalties should follow the example of the 2015 case where action by Hertfordshire Trading Standards against a well known retailer, found to be selling non-compliant Hi-Viz clothing, resulted in a fine of £15,000 plus a confiscation order of over £42,000 plus costs. Confiscation orders are not normally seen in these types of cases, being normally applied in proceeds of crime recovery, but this confiscation reflected the reality that the products were fraudulently being placed on the market. Penalties under this structure and scale will act as a very powerful disincentive to economic operators ignoring their responsibilities and placing individuals at risk. BSIF will then be able to highlight these cases to the wider market encouraging all to discharge their obligations and ensure that users are kept safe.

3 We call on the Office for Product Safety and Standards to recognise that PPE must be removed from the market if it cannot immediately be evidenced that it complies with Regulation 2016/425. As a minimum this must be applied to PPE in Categories II and III which require independent conformity assessment by Approved Bodies scoped for that purpose.

4 We call on the legislators to take action on the unethical and immoral practices enabled by the illegitimate defence of “innocent publication” allowing internet portals and sellers to avoid responsibility for the products that they promote, profit from and assist in placing on the UK market. In this call to the legislators we would stress that social media platforms be they Twitter or LinkedIn must be included in any reform as they increasingly facilitate the sale of PPE. Action in this area by UK legislators would show global leadership and be welcomed universally.

5 The confusion of responsibility as to who is the relevant enforcement authority must be addressed. Currently HSE are responsible in an “at work/occupational” situation with Trading Standards being responsible when PPE is sold to the private consumer. Supply chains, **where the problem and the solutions lie**, do not effectively differentiate between the two different scenarios, so one enforcement agency for one supply chain, as opposed to two enforcement agencies is an essential change. HSE, of course, should remain as the responsible authority for all workplace safety and health practices, including what and how PPE is used.

The non-compliant PPE will exist in the supply chain prior to its sale for occupational use and the problem should be addressed, in that supply process, prior to it reaching the wearers. Trading Standards have the experience of dealing with traders and in a wide range of supply chains, HSE do not have a history of involvement or access to suppliers and therefore it is our contention that Trading Standards must be the primary enforcement authority for PPE.

Keeping PPE which does not conform to the Regulation, off the UK market and ensuring users are kept safe must happen now. It is achievable without significant cost or disturbance. Following the 5 steps above will deliver significant improvement.