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Experts in Safety

Towards a Safer Future

Arco's vision for a new, fit for purpose product safety framework

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Foreword from the Chairman of Arco

As we learn to live with the Covid-19 pandemic, it's important to continue our work on what can be learnt and improved for future emergencies. We must learn lessons from the pandemic itself, but there is an acute need to look at the structures that protect us from everyday risk, from substandard goods and unscrupulous businesses. Now is the time to call out for the creation of a new product safety framework.

For those of us in the safety sector, the quality, efficacy and standard of Personal Protective Equipment (PPE) has always been an important part of our everyday life. The reality is that safety, whether in the home, the workplace, or in public places, should never be viewed as a matter for compromise.

Unfortunately, we know from experience that as hard as officials, industry and regulators all worked together to protect users of PPE during the pandemic, sub-standard safety equipment still entered the UK market. This put people's lives at risk, and we cannot rule out that in some cases it may have cost lives. That's why we feel it is important to continue our work on what lessons can be learnt from the pandemic, to ensure the country can be better prepared for future emergencies.

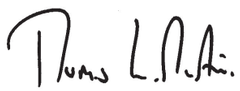
The world in which we operate is changing, with more people buying and using complex and potentially dangerous products in the home and workplace. UK product safety regulation has always been world leading. But it is important that it is reviewed and updated to deal with the growth of the digital economy and new, emerging products, especially from overseas markets whose protections may not be as robust as our own. We are at the beginning of the Fourth Industrial Revolution and it is vital that our regulatory system remains relevant.

As market leaders we are obligated to present our vision for a stronger product safety framework, well equipped to weather the next crisis, and resilient enough to protect people as they go about their lives. For many years we have been lobbying to improve and enforce safety regulations and standards, and it is our duty to contribute our expertise at this critical time. Our recommendations reflect the work of our experts, our experience as the UK's leading safety company, as a major importer of regulated goods, and as a supplier to the UK Government and public sector. It reflects what we have said to Government, to Parliament and to our colleagues across the sector.

We are delighted that BEIS and OPSS have recognised many of the themes and concerns we set out in this paper in their initial response to the Product Safety Review, and we look forward to working constructively with them and more widely across Government as they begin the work of developing proposals for overarching legislative and regulatory reform.

Together, we can build a safer future.

Thomas Martin



Chairman, Arco

About Arco

Arco is the UK's leading supplier of PPE and professional safety services. Founded in 1884, we are a family-owned business committed to delivering our core purpose of keeping people safe at work.

Arco has a team of experts with specialist knowledge dedicated to keeping people safe at work. Our experts are involved at every stage in the safety and PPE equipment supply chain. From our product experts who ensure the correct product specification, to sourcing and procurement specialists, including a dedicated team based in Xiamen, China, through to our quality assurance team who ensure compliance in our own independently accredited laboratory. All underpinned with expertise in warehousing and logistics.

Product Expertise

Our experts have a deep knowledge of safety, hazards and personal protective equipment, this allows us to provide expert advice on complex issues to corporate clients, governments and public bodies. Our senior staff have a presence on the board of the British Safety Industry Federation (BSIF) and represent the BSIF at the European Committee for Standardisation and the International Standards Organisation. They are also members of several British Standards Institution (BSI) protective equipment committees.

Quality Assurance

We are committed to providing safety equipment that is genuine and compliant with necessary standards and regulations. We have invested in our own product assurance laboratory, which is both UKAS and SATRA independently accredited and our product assurance process provides confidence to our customers that the products we sell are fully compliant. Our team in China assist with sourcing, plus they audit and inspect our own brand manufacturers. As a member of the Ethical Trade Initiative (ETI) we only work with suppliers who share our standards when it comes to ethical sourcing and modern-day slavery.

Supply Experience

We work with 110,000 customers of all sizes, across sectors and industries in both the public and private sectors. We help businesses understand the risks that they face and provide the right solutions for them. We have a strong heritage and expertise in supplying the public sector and are proud to hold many key framework agreements including NHS Supply Chain, Crown Commercial Service (CCS) and in Scotland, Scotland Excel. In times of crisis, we are experienced in the provision of expert advice and appropriate and compliant safety products, examples include, foot and mouth, mad cow disease, swine flu and Ebola.

Logistics Excellence

Our National Distribution Centre holds stock of more than 22,000 products and recently underwent a £30 million expansion to double our stockholding capacity and enhance our service levels. We despatch orders to over 50,000 sites, every day despatching over 8,000 consignments plus 150 pallets to the UK and Ireland.

The global opportunity

The UK has a strong product safety infrastructure with robust standards and internationally, has led the way on safety for a long time.

However, there are vulnerabilities that have arisen with:

- the growth of the digital economy
- challenges posed by post-Brexit regulatory changes
- the continued reliance on a dispersed and fragmented system of regulation, monitoring, compliance and enforcement.

Yet there are also major opportunities as the UK seeks to forge its own path following our departure from the European Union. These include the ability to develop a new space for innovation for industrial products, and to leverage our world-leading expert base to build digitally accessible knowledge hubs and harness the efforts of safety-focused innovators.

The creation of a new product safety framework is a task that we should see as lasting beyond the pandemic – and necessitates a full assessment of what is working, and what is not.

Respirator

Surgical face mask

Face covering

Current Challenges

Highly differentiated risk and overlapping standards

The General Product Safety Regulations 2005 (GPSR) requires all products to be safe in their normal or reasonably foreseeable usage and enforcement authorities have powers to take appropriate action when this obligation isn't met.

But PPE (alongside other specifically regulated categories of products) presents a significant risk to the individual user if it fails to operate as specified. For Category II and III PPE in particular (as per Regulation 2016/425 as amended in UK law) the result can be death or serious injury if they fail in use.

As it stands, the safety framework for products does not adequately account for highly differentiated risk. There is a complex regulatory framework and the overlapping requirements are an issue.

Regulatory gaps

We are aware of incidences where individuals and organisations have sought specific guidance on a category of product and finding none, have incorrectly assumed that no standard applies, rather than the cross-cutting provisions of the General Product Safety Regulations 2005 (GPSR). With the growth of the digital economy and the lowering of market barriers, this is an issue that is likely to only get worse.

A fragmented system

The interaction between different regulatory frameworks can also be difficult to understand. One illustrative challenge of the past year has been wide-spread issues with understanding the differences between PPE (broadly with the purpose of protecting a user) and medical equipment (broadly with the purpose of protecting the subject) and the accompanying regulatory standards surrounding those definitions.

Respiratory masks are PPE and are manufactured to recognised standards for PPE. Surgical (or face) masks are not PPE, but medical devices manufactured to specifications for medical/ surgical masks (which are deemed as medical devices in accordance with the EU Medical Device Regulations). Face coverings added an additional confusion, when introduced they were not manufactured to a recognised standard and did not contain CE marking.

Images of PPE and workers are for representation only.

Building a product safety framework for the future

Whilst the foundations of the current product safety framework are solid, there is a need to make adjustments to the specific way in which it is organised, making it easier to navigate, harder to circumvent and ready for a digital future.

We have grouped our recommendations into six key areas of opportunity. By making structural changes, we can eliminate loopholes, unlock the full potential of the UK's safety sector, and ensure that the product safety framework remains fit for the future.

1. **Establishing an authoritative source of guidance.**
2. **Strengthening the paper trail documenting a product's safety.**
3. **A new supplier registration framework for PPE.**
4. **The right regulatory bodies in the right place with the right resources.**
5. **Building a safe space for innovation.**
6. **Regulation for a digital economy.**

1. Establishing an authoritative source of guidance

For those seeking to follow the rules, and those seeking redress once when things go wrong, it is difficult to understand what specific regulations apply, and where to go for support.

One of the principle challenges for those who deal with regulated goods and who are seeking to navigate the product safety system is that there is no authoritative source of guidance. There is currently no accredited official body that can be consulted to gain an answer to technical questions on certifications.

Notified bodies cannot (and should not) advise on the application of the rules, only assess them.

Test houses are commercial entities and whilst they can offer support, this is often dependent on commercial considerations, such as the size and relative value of a customer.

Similarly consumers' understanding of the markings of a safe product that has gone through appropriate testing and met the relevant requirements is extremely limited.

Understanding will be challenged further as Britain continues to chart a future beyond the EU, with the likely divergence from common standards and practices that have been in place for decades. There is a need for far clearer information to be displayed, and for greater action to ensure that retailers are acting responsibly, particularly when marketing directly to consumers.

We recommend:

- **The establishment of a nominated authority to provide guidance to businesses dealing with regulated goods.**
  This should be delivered by an accredited advisory body who has proven competency, and nested within the notified body ecosystem.
- **The creation of a hub to facilitate consumer awareness and provide a simple, one-stop hub for those in need of guidance.**
  The US Consumer Product Safety Commission operates a user-friendly safety hub, bringing together advisory notices, education sources and regulatory guidance, a similar hub should be established in the UK.
- **The introduction of a customer-focussed helpline that is able to deal with a query or refer a complaint to an officer able to take action.**
  This could be based on the model used by HMRC.
- **The development of a communication platform for businesses, requiring them to specify action against cases raised and to track Government progress on determinations.**
  This could be built into the aforementioned hub and similar to the modern slavery portal being developed by the Home Office.
- **Clear promotion to consumers of sources of support where engagement with digital retailers falls short of requirements.**

2. Strengthening the paper trail documenting a product's safety

Despite extensive regulations governing record keeping, there are clear loopholes. This allows for sub-standard goods to move past surveillance systems and into the hands of consumers.

Currently, there is a significant, dispersed paper-trail documenting a product's safety. At the apex of this system is a 'Type Approval Certificate' (i.e. a UKCA or CE certificate), produced by the entity placing the product on the market and not the appropriate certifying body. Certificates issued by the notified body on the relevant aspects are far more valuable in illustrating to professionals that a product is legitimate and fully compliant, as are the testing reports that underwrite that determination.

Neither the CE or UKCA Type Approval Certification requires a visual identification of the actual product tested. Therefore, to conclusively determine that a product offered is the same as the one certified, a purchaser needs to access the test reports. With a globalised supply chain this is challenging, and we believe this allows uncertified products to slip through and enter the market using fake certification.

Best practice is to ask for a full paper trail, but this can be challenging. During the pandemic, some suppliers refused to provide this information on request as we sought new sources of safety products to supply onward to customers. During this period we also identified a number of PPE products with fake Declarations of Conformity, particularly for products retailed online. Attempts to ramp up supply in such a system will thus result in a much heightened risk of substandard supply.

We recommend:

- **Certification documents should carry a photograph of the product as tested.**
  This would allow economic operators to clearly and easily determine that the appropriate testing and certification has been done for a specific product.
- **Clearer rules, backed in the regulations should be added to govern a clear documentary trail on any changes needed to bring all marketable versions of a model into compliance.**
  With active surveillance by OPSS and meaningful penalties for non-compliance.
- **A return to a system of annual surveillance of importers and distributors, with a requirement for manufacturers to ensure their products remain in compliance as they enter the market, and to seek renewed certification if there is a material change to their composition.**

Images of PPE and workers are for representation only.

3. A new supplier registration framework for high-risk PPE

PPE is worn to protect individuals from specific hazards. When products fall short of safety standards, the wearer is exposed to those hazards, which may result in a risk of illness, injury or death. The risk of serious injury or death is too high at the highest category of PPE to treat these the same as inert goods.

Some PPE products carry significant risk to the individual user if they fail. Category II and III PPE in particular (as per Regulation 2016/425 as amended in UK law) can result in the death or serious injury if they fail in use.

Registration of suppliers

The registration of Category II and III PPE suppliers would help ensure that a supplier is capable of providing compliant products.

Our view is that there should be a central register, which would be held by either the Office for Product Safety and Standards (OPSS), or the Health and Safety Executive (HSE).

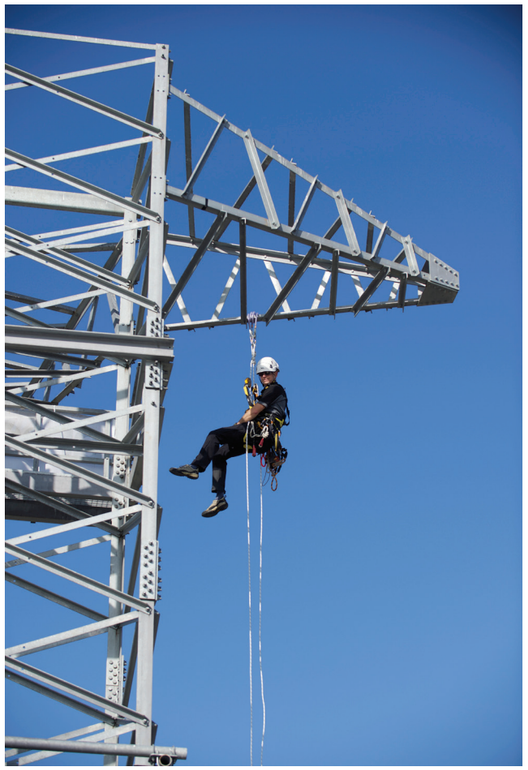
Suppliers would pay a fee to be listed on a central register, in the same way that listing with the Medicines and Healthcare products Regulatory Agency (MHRA) works for similar categories of medical devices.

In the event of future emergencies the Government would have a list of approved suppliers and approved products and therefore there would be no need to make panicked spot buys from suppliers about whose qualifications and expertise they were uncertain.

Either regulatory authority would need to be sufficiently funded to do this, since at present there is concern across the safety industry about whether either body is suitably resourced.

We recommend:

- **All manufacturers and distributors of Category II and III PPE be required to hold a license.**
  Such a license would assure buyers that they have taken all steps to ensure that their products meet relevant standards, with a clear chain of custody across the supply chain. Continued compliance with all relevant regulations, as well continued due diligence on their own supply chain, should be a condition of such a license.
- **A statutory list of safe manufacturers, suppliers and distributors who are fully compliant with all relevant regulations.**
  This list could be established by the OPSS and could act as the nucleus of a regulated PPE sector, and the basis of efforts to upscale manufacturing and supply in a crisis – eliminating the risk of opportunism and profiteering.



Images of PPE and workers are for representation only.

4. The right regulatory bodies, in the right place, with the right resources

Regulation underpins the integrity of the safety sector. But bad regulation is counterproductive, and a good regulator must be appropriately resourced, empowered and focused.

The most effective product safety system assures the integrity of the manufacturing and supply process as a foundation, and then creates a robust process by which all products are tested, certified and supplied by reputable, capable organisations. Whilst you cannot offset poor product standards by enhancing manufacturer standards, a focus on the organisations that supply them creates a stronger base for a safer market.

Protecting the domestic market from poor quality product

A focus on supply is challenged by the prevalence of imports, often from low-cost countries. Non-branded, low-standard and low-cost goods are a principle risk factor, and we have identified fraudulent and non compliant products on the UK market. This is likely to remain a source of vulnerability.

Both direct production of PPE (via emerging technology like 3D printing or home production) and the reuse of PPE in the consumer market can create significant product safety issues and is a growing area of concern. Regulators must act now to prevent cottage industries of amateur manufacturers taking root.

There are questions over the standard liability for sub-standard product, and an open question as to where this should be pegged.

Conditions of use will play a major role in determining how long a product is viable, let alone safe. There are challenges in assigning a hard and fast rule, or even worse, a universal statutory definition, for manufacturer liability on safety. Whilst two years is a generally effective guide, product categories will widely vary either side of this.

Sharing best practice across effective regulators is also important. The Government should consider the effective operation of the HSE's Fees for Intervention scheme, which does a lot to encourage responsible operation in the first instance, and look at a similar system for product safety.

We recommend:

- **Port of entry checks should be strengthened on the basis of market intelligence, coordinated through the OPSS.**
  Plus all imported PPE should be required to list a UK address for an accountable importer as well as a clear link to the original manufacturer in the paper trail.
- **Online platforms should be monitored to reduce the risk of a proliferation of sub-standard designs, amateur guidance, and the development of 3D printing of PPE.**
  The OPSS must be appropriately resourced, empowered to monitor and able to act robustly against attempts to enter the market from such a basis.
- **Ministers, on the advice of OPSS, should be able to flex a standard definition of product liability via secondary legislation.**
  This should take account of situational considerations, for emerging technologies that may present unique use cases.
- **Where a distributor has sold a good that has been found to be sub-standard, a fee should be levied.**
  The financial penalty should be levied on the distributor or manufacturer (whoever is determined to materially be at fault) in order to facilitate any necessary regulatory action.
- **Where supply is via an online platform consideration should be given to holding the platform liable.**
  Particularly in cases where the supplier is located outside of the UK and selling directly to consumers without a UK distributor.
- **OPSS should hold discretion on publication where the threshold for recall is not met –**
  but where there is a statutory requirement to give primary regard to the safety of consumers.
- **OPSS officers should be empowered directly to deliver enforcement activities**.
  This would reduce the need to rely on Trading Standards, HSE, HMRC and the police (as was originally mooted during the passage of the Ivory Act).

5. Building a safe space for innovation

The pandemic has shown the value of agile research and development. The focus now should be on creating safe spaces for innovation and testing free from the necessary burden on regulation, so that manufacturers can develop and deploy new tech faster to keep people safer.

The structural challenge for products that carry a use risk and necessitate a regulatory framework is that of a safe standard to form the basis of certification for use. The pandemic required the easement of some rules around trial products, to enable manufacturers to rapidly develop new approaches to the emerging challenges brought by Covid.

Many of these changes were used to best effect in the medical and healthcare space, as regulated by the MHRA. This allowed the rapid development of new testing methods faster than would otherwise have been feasible, whilst retaining a rigorous standard.

Whilst there were easements in PPE regulations, these were more focussed on reducing supply constriction than allowing for the development of new approaches to PPE. There are particular concerns surrounding testing new approaches to industrial PPE as their deployment into a situation to allow effective testing and user trials could pose a risk to individuals.

We recommend:

- **A new "Development Framework" should be established to allow industrial PPE to be tested in a risk-assessed environment, akin to a clinical-trial mechanism.**
  This would allow for the effective testing of PPE proven to be safe at a baseline level, but that departs from the established standard. This could be overseen directly by the OPSS or HSE, inviting a higher level of supervision than the certification of products to existing standards, and would offer a valuable opportunity to develop new approaches to safety.

6. Regulation for a digital economy

Our current product safety rules were written in an analogue world there is an urgent need to look at ways to reduce the risk but exploit the opportunities of digitalisation.

The current treatment of online retail platforms allows them to undermine safety standards. Since they are classed as digital retail platforms, they do not have to take responsibility for the quality or the compliance of third party products sold through their platforms.

We believe that existing definitions of supplier, manufacturer and distributor are redundant in the online space. There is a need for a new categorisation that recognises that whilst online platforms are not, by definition, the supplier or distributor, they are a vital part of the chain of custody of regulated goods and must bear responsibility.

Currently online platforms are not held responsible for delivering product recalls, relying on legal definitions that do not consider them to be the seller but just a platform. Difficulties also come from requiring distant suppliers to manage the recall of dangerous products already in the UK without either a UK presence or effective UK communications infrastructure. When recalls of defective PPE is necessary, lives can be at risk.

It is rarely made clear on online platforms where responsibility for product safety lies until attempts are made to identify an issue, at which point it is common to be redirected away to another element of the supply chain. It is also unclear from the perspective of the consumer what they ought to be looking for to determine if a product is compliant and if a platform or supplier has taken appropriate action to ensure a product is safe.

We recommend:

- **BEIS should review the allocation of product safety responsibilities in relation to online retailing, legislating, if necessary, to require online platforms to hold clear UK contact details for suppliers.**
  Where these do not exist as the supplier imports directly to the consumer market via the online platform, the platform should be held accountable as the UK point of entry, with the regulatory requirements that entails.
- **OPSS should be empowered to require timely cooperation from online platforms when action is required to remove unsafe products.**
  The Government should encourage online platforms to give access to OPSS to do so directly.
- **The Government and legislates to require online platforms to facilitate product recalls as if they were the UK point of sale of a supplied good.**
  OPSS should be empowered, by law, to hold platforms to account for doing so on the same terms as bricks-and-mortar distributors.
- **Online retailers should be required to adopt a precautionary principle.**
  If concerns are raised, sales should be required to be halted before either the retailer or regulator can investigate safety concerns and clear it for a return to sale or removal. This should, at the least, involve a best effort obligation to contact the customer using the information they supplied during the sale, and to display a digital point of sale notice if not.

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