

From the Chief Executive

Sarah Albon
Health and Safety Executive
7th Floor Caxton House
6-12 Tothill Street
London SW1H 9NA

Sent via email

25 November 2020

Rt. Hon. Stephen Timms MP
Chair of the Work and Pensions Select Committee
House of Commons
London
SW1A 0AA

Dear Mr Timms,

HSE'S WORK ON APPROVING PERSONAL PROTECTIVE EQUIPMENT SUPPLIED BY PESTFIX

Thank you for your letter of 19 November to Sarah Newton, in relation to the BBC News story concerning supply of Personal Protective Equipment (PPE) by Pestfix. Sarah has asked me to respond.

You will be aware that supply and use of PPE is regulated to ensure that relevant standards of protection are met and maintained to ensure appropriate levels of worker protection when PPE is relied on as a means of managing risk that cannot be eliminated in other ways. Part of the regulatory process is that of conformity assessment through European Notified Bodies and the use of the CE mark to confirm that items of PPE are in fact of the required standards.

In response to the Sars-CoV2 pandemic the EU made a recommendation to agree derogations (regulatory easements) for PPE that is not CE marked to be allowed for supply in health care provided relevant Market Surveillance Authorities (MSA) were satisfied that it met the essential health and safety requirements (EHSRs) for protection against Sars-CoV2. As the independent regulator for workplace health and safety HSE are the MSA for PPE supplied for use at work.

To enable full and proper assessment of the standards of PPE that were being put forward for supply under this EU easement, HSE established a specific Unit of regulatory, technical and policy specialists to support the Government supply chain and wider PPE supply to healthcare. This established a process of technical assessment and senior level decision making for every product that was being put forward for supply under these easement arrangements. Throughout this period, we have only permitted supply of PPE that is in fact safe and has been demonstrated to meet the necessary EHSRs and have prevented items that do not meet the required standards from entering the supply chain.

In response to the specific questions you raise:

- 1. Did HSE staff raise any concerns with you or your predecessor at the time about pressure coming from the Government? If so, how did the organisation deal with these concerns? a. Did the pressure from the Government play any role in HSE's decision to approve the PPE from PestFix for use, or in the timing of that decision?*

The reference in the BBC article to “pressure” appears to have been made by someone outside of HSE. At no time in the management of PPE supply have any HSE staff indicated that there were feelings of pressure being applied to make specific decisions, to change decisions, or to accept lower standards than required of PPE. In particular the senior Decision Making Group (DMG) arrangements require unanimous agreement of the three decision makers (HSE Chief Scientific Advisor, HSE Chief Medical Advisor, and HSE Head of Operational Strategy) that the PPE meets the relevant standards before supply is agreed. The DMG have not felt any pressure being applied to make specific decisions.

HSE have worked with Government departments and the wider supply chain to ensure that we collectively meet the needs to the NHS to have adequate supplies of safe PPE, we have recognised the need to work at pace to do so, and set up our PPE Unit to work on a 7 day a week 16 hours a day basis to ensure we could meet these needs. The process of technical assessment for PPE products has often involved iteration if, for example, adequate information was not initially available to demonstrate the items met the required EHSRs. In such cases HSE may have asked the supply chain to obtain further information, or to arrange for further testing, to verify the product. In these cases, products that initially had insufficient or incorrect information provided may have been subsequently reassessed and agreed for supply when those gaps had been addressed.

- 2. Are you aware of other recent instances of HSE officials being “pressured” into taking a particular decision by a government department? Does HSE have specific processes in place for how it should respond in these situations?*

We do not have any instances of being pressured into making or changing decisions. Throughout the pandemic HSE has maintained its independence and applied the principles that PPE must in fact be safe before it can be permitted for supply. Our process for ensuring this in relation to PPE supply includes the formation of the Senior DMG as previously described to ensure that regulatory easement granted by HSE as the MSA are valid, justified and consistently applied. The DMG also acts as the final arbiter should any of these regulatory decisions be challenged by suppliers.

Like all Civil Servants HSE employees are expected to act in accordance with the Civil Service Code and these principles are particularly pertinent to the process we have for PPE supply. Acting in accordance with the code is a fundamental part of ensuring decisions are made with the utmost propriety. Our own internal guidance to our staff also highlights how they can raise a concern under the code and we would expect this route to be used in a matter as serious as pressure being applied that would effectively lead to supply of sub-standard PPE that could ultimately put others at risk.

- 3. When suppliers are processed through the “high priority” lane, does this change the safety assessments that HSE carries out on PPE, or the amount of time that you have to make these assessments*

While the procurement process operated by Government may have had a “high priority” lane to identify and assess potential suppliers HSE has not operated such a system for technical evaluation of PPE. All requests for regulatory easement for PPE supply are processed in the same way. The exact time taken for making assessments may vary according to the complexity and availability of relevant data. The scrutiny and level of technical assessment applied by the technical teams and the assurance applied by the DMG has been consistent throughout. When the volume of requests was at its height this process was carried out using the 16 hours per day, 7 days a week operation described above. The processing of applications was initiated on receipt and assessment through to decision making was handled accordingly. This has now been scaled back to routine Monday to Friday hours as the current level of requests can be managed in these timescales. We have however worked closely with the NHS supply chain and the cross-government PPE team and in situations where this liaison highlighted scarcity of particular items we would aim prioritise these over other requests received on the same day.

Ultimately, while the circumstances at the height of this supply situation were clearly a pressurised environment, and it was impossible to be unaware of the urgency of supplying PPE to front line health care workers, we also understood the importance of making robust and reliable regulatory decisions, and at the heart of this we knew health care workers would only be protected if they received PPE that was effective. All of these decisions were firmly made with that in mind.

Thank you once again and I hope you find this letter useful.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sarah Albon', with a stylized, cursive script.

Sarah Albon
Chief Executive, Health and Safety Executive



Work and Pensions Committee

House of Commons, London SW1A 0AA

Tel 020 7219 8976 Email workpencom@parliament.uk

From the Chair

Sarah Newton
Chair, Health and Safety Executive

19 November 2020

Dear Sarah,

I am writing to you about a series of emails between HSE and the Department for Health and Social Care (DHSC), obtained by the BBC via a Freedom of Information Request. The BBC reports that, over the summer, the Government pressured HSE officials to approve Personal Protective Equipment supplied by PestFix for use in the NHS.

The emails suggest that officials at HSE were placed under “political” pressure to approve the equipment for use, and in at least one case asked to make an incorrect statement about whether the equipment complied with the relevant standards. These are concerning reports, and it is essential that HSE is empowered to make impartial and independent decisions free from the influence of Ministers or officials.

It would be helpful to have a response to the following questions:

- 1. Did HSE staff raise any concerns with you or your predecessor at the time about pressure coming from the Government? If so, how did the organisation deal with these concerns?**
 - a. Did the pressure from the Government play any role in HSE’s decision to approve the PPE from PestFix for use, or in the timing of that decision?**
- 2. Are you aware of other recent instances of HSE officials being “pressured” into taking a particular decision by a government department? Does HSE have specific processes in place for how it should respond in these situations?**

The National Audit Office has noted that there was an urgent need to procure PPE quickly during the first few months of the pandemic, when demand for PPE was rising sharply. It also said that some procurement during the pandemic has come through a “high priority” lane, a route set up to assess and process potential PPE suppliers that were suggested by

government officials, ministers' offices, MPs and members of the House of Lords, senior NHS staff and other health professionals.

The NAO said that the "cross-government PPE team considered that leads from these sources were more credible or needed to be treated with more urgency." PestFix was processed through the high priority lane, although that classification was because of a mistake by the cross-government PPE team.

3. When suppliers are processed through the "high priority" lane, does this change the safety assessments that HSE carries out on PPE, or the amount of time that you have to make these assessments?

The Committee would appreciate a response by Friday 27 November.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Stephen Timms', with a stylized, cursive script.

Rt Hon Stephen Timms MP
Chair, Work and Pensions Committee