



Personal Protective Equipment
Horizontal Committee of Notified Bodies Coordination Group

Mr **Mehdi HOCINE**
Unit H.2 – Machinery & Equipment
European Commission, DG GROW

Subject: Formal request for Communication infrastructure and Formal legislative change

Communication infrastructure

In September 2020 the HCNB called for better communication between the authorities of the European Union and Notified Bodies, particularly to seek effective consultation on any proposed or planned changes to guidance or primary legislation.

While the European Commission Policy Officer for PPE has attended to present information at the HCNB meetings and we appreciate this, additional requests made for this to be formalised have not been met.

Formal legislative change

The formal legislative procedure via the parliament and council is being circumnavigated by reinterpretation of the letter of the law on the matter of implementation of Module C2, within PPE Regulations Guidelines version 3. This interpretation has been challenged by the HNCB sub-group 'Ad-Hoc C2 D' and of many industry actors.

Specifically, the Module C2 proposal is counter to the Commission measures to 'Help small and medium-sized enterprises and start-ups to grow' and 'Ensure a culture of compliance and smart enforcement to help deliver a true single market'. By requiring production with no commercialization until a full Notified Body Product Check Report is produced, you create a barrier for SMEs and start-ups that cannot sustain debts incurred from capital investment, salaries, material and energy costs that larger established enterprises may. By creating this new barrier to trade, that creates a perverse incentive for SMEs to illegally place product on the market and seek forgiveness via (EU) 2016/425 Article 41 Formal non-compliance measures.

The adoption of change via guidance also appears to be against the principles of the New legislative framework, to set clear and transparent rules - if the legislation is unclear, then the legislation must be changed.

Therefore, we request that the contested changes of the Regulations Guidelines version 3 be considered in the formal legislative change process, such that democracy is served, transparency is honoured, and clarity is reached.

Yours respectfully,

date 11.03.2024

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