To:
Lorena Boix Alonso - Deputy Director General for Health
responsible for Directorates B, C and D (SANTE.DDG1)

CC:
Florina Telea – Head of Unit A4 Multilateral International Relations
Csaba Kontor – Policy Assistant Cabinet of Commissioner Várhelyi
Alexandr Hobza – Cabinet of EVP Séjourné
An-Sofie Ronnlund – Cabinet of Commissioner Zaharieva

Ref: Proposal to amend Annex I of EU Implementing Regulation 2021/632

18 November 2025

Dear Ms Boix Alonso,

On behalf of the Life Science Manufacturers Association (LSMA), MedTech Europe and Verband der Diagnostica-Industrie (VDGH), we wish to express our concern regarding the proposed changes to Annex I of EU Implementing Regulation 2021/632 laying down the rules for applying border controls on products of animal origin. Together, our associations represent industries manufacturing and distributing materials and products used in the context of medical and in-vitro diagnostic devices, medicinal products, as well as reagents for general research and food testing.

We kindly ask the European Commission to consider delaying the adoption of these proposed changes so that their implications can be fully assessed. Broadening the scope, as proposed, would have a substantial negative impact on the EU's Life Sciences ecosystem and, subsequently, on the availability of safe medicinal products and critical medical devices used for microbiological testing, immunophenotyping, and molecular diagnostics. Any delay or disruption could directly affect patient care, the functioning of public health systems, and food safety.

The amendments to the Implementing Regulation seek to expand the scope of products subject to control to a number of compounds and products required by the Life Science industry to support manufacturing and research in Europe. Examples include, but are not limited to, biopharmaceuticals, medical devices, animal health, and industries involved in food safety. While we understand the intention to mitigate risk, the current approach does not sufficiently take into account the highly processed nature of the impacted products. Mandatory border inspections with qualification descriptions that are not fit for purpose are likely to introduce delays that reduce the availability of concerned products, some of which have a short shelf life. This could represent a deviation from the original intent of the regulation, which is designed to protect food and feed chains.

We also note that this proposed amendment has been announced without prior consultation among Life Science stakeholders. We believe that engaging with industry would help ensure that the measures are practical and aligned with the EU's ambition to make Europe a global leader in life sciences by 2030, as outlined in the EU Life Sciences Strategy. Moreover, on previous occasions, Commission officials have informed us that "purified antibodies are not considered as being an animal by-product or a derived product" (cfr. SANCO/7132/2012), yet these now appear to be included within the scope.

We remain concerned that should this expansion proceed without adequate preparation and industry consultation, imports of life science-related products—critical to fundamental research, biopharmaceutical R&D and manufacturing activities, as well as diagnostics development and manufacturing within the EU—will be disrupted. This is expected to impact, for example, items ranging from cell culture media vital to the production of vaccines, the development of new therapeutics and biologics, to bacterial contamination monitoring devices critical for food safety, as well as analytical kits, reagents and processing supplements.

Furthermore, without adequate preparation, for example by updating the adjacent animal by-products Regulation (EU) 142/2011 and Qualification Notes, and issuing suitable guidance, Member States will be unable to process imports, leading to the halting of consignments at the border. We offer below some of the most salient potential consequences from the supply disruption of these critical products.

Specific consequences of the disruption of life science-related products supply would include:

- Impairing the ability of drug and food manufacturers in the EU to comply with criteria for hygienic manufacturing and sterility testing and eventually posing a risk to the availability of safe treatment of patients in the EU, as well as of safe food for EU consumers.
- Disrupting critical processes in biomanufacturing that have been established on the basis of cell culture media, including complex mixtures containing animal-derived components.
- Unavailability of these cell culture media will create additional upheaval as media formulations form an integral part of the marketing authorisation of medicinal products. Reformulating medicines due to the unavailability or shortage of these Life Science components will force the need to file a variation to keep a medicine on the market, taking several years for development and revalidation, and at a high cost to both manufacturers and ultimately patients. It will also exacerbate the present shortage of medicinal products.
- Unavailability of immunological products used as research and quality control tools will impair the progress of scientific research into products for medicines, diagnostics, and treatments aimed at enhancing healthcare outcomes, such as CAR T-cell therapies, which are critical for treating blood cancers and potentially other diseases.
- Undermining the ability of healthcare systems to conduct essential microbiological testing, immunophenotyping, and molecular diagnostics;

thereby directly compromising patient care and the effective functioning of public health services.

For the reasons stated above:

- **We urge the European Commission to delay adoption of the proposed change to allow time to consult with our industries and ensure the creation of an implementable set of rules that does not impede Europe's ability to provide medicines and medical devices used for microbiological testing, immunophenotyping and molecular diagnostics to European and global health systems and patients.**
- **We ask the Commission to update the adjacent animal by-products Regulation (EU) 142/2011 to enable the broadening of the scope. In addition, we ask that third countries be permitted to update their registration scheme first.**
- **We recommend a revision of the associated Qualification Notes to provide sufficient clarity on the risk that the proposed changes intend to mitigate, so we may jointly find the most suitable resolution to meet the Commission and Member States' objectives.**

We would welcome the opportunity to discuss this matter with you in greater detail at your earliest convenience.

Best regards,

John Clarke LSMA President	Oliver Bisazza Chief Executive Officer MedTechEurope	Dr. Martin Walger Geschäftsführung VDGH