EU COMMISSION CALL FOR EVIDENCE ON BIOTECH ACT

A.I.S.E. position

06 June 2025

A.I.S.E., representing the cleaning and maintenance products industry, welcomes the European Commission's opportunity to contribute to the Call for Evidence on the *European Biotech Act*. Biotechnology plays a vital role in our sector, particularly through white biotechnology and microbial applications, that enhance product performance.

A.I.S.E. urges the European Commission to ensure that the Biotech Act supports the full potential of biotechnology across all relevant industries, including ours. This position paper builds on A.I.S.E. contribution to the Stakeholder Questionnaire – *Regulatory framework for biotechnology and biomanufacturing in the EU* – and provides additional reflections and recommendations for the ongoing legislative process.

(final) A.I.S.E. submission BioTech

Scope of Biotech Act

A.I.S.E. strongly supports the European Commission's ambition to reinforce and enhance the role of biotechnology and biomanufacturing within the European Union. However, we emphasise the importance of ensuring that this ambition extends beyond the pharmaceutical and healthcare sectors, including a broader range of industries in the scope of the upcoming Biotech Act. Biotechnology is a key innovation driver in numerous industries, including ours. The detergents and cleaning products sector is a prime example of how biotechnology, particularly white biotechnology[1], can be leveraged to support the EU's sustainability objectives. Examples of biotechnologies used in detergents products correspond to microorganisms, enzymes or other byproducts derived from biotechnologies production processes (e.g. biosurfactants).

The European Commission's Communication *"Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU"* already acknowledges the cross-sectoral potential of biotechnology. The forthcoming Biotech Act must reflect this reality by **ensuring that its legal scope includes all relevant industrial applications of biotechnology**, including those used in detergents and cleaning products.

A.I.S.E. therefore urges the European Commission to ensure that the BioTech Act explicitly includes a wide range of sectors—beyond pharmaceuticals—such as the detergents and cleaning industry. A broad and inclusive scope will unlock the full potential of biotechnology to foster innovation, promote sustainability, and stimulate economic growth across the EU.

[1] The industrial production and processing of chemicals, materials, and energy using living cell factories, like bacteria, yeast, and fungi. https://www.idtechex.com/en/research-report/white-biotechnology-2024-2034/959

Enzymes

Enzymes meet the needs of modern society for convenience without compromising health and safety. Enzymes derived from biotechnological processes are widely used in laundry and dishwashing detergents and provide essential benefits and pivotal function for our products:

- ***Enhance cleaning efficiency*** at lower temperatures, reducing energy consumption for heating water during washing cycles.
- ***Positive environmental impact*** significantly lowers carbon dioxide emissions linked to transport since the use of enzymes allows products to be more efficient and more compact
- ***Support sustainable production*** by using biodegradable, renewable resources.

Furthermore, allergies among consumers to enzyme-containing laundry and cleaning products have not been reported for over 50 years. Evidence involving many thousands of consumers has shown that the use of enzyme-containing detergents does not result in sensitisation to enzymes. Due to these reasons, A.I.S.E. recommends assessing the use of enzymes in a risk-based manner and not to restrict them based on their hazard classification.

Microorganisms

Microorganisms, particularly microbial cleaners, are a key driver of sustainable innovation in the detergents and cleaning sector. These products offer effective, sustainable cleaning solutions and contribute to the EU's strategic goals of reducing dependency on external suppliers and fostering local biomanufacturing. However, recent regulatory proposals risk undermining this progress. Restrictions on the applications or formats of microbial cleaners could lead to the withdrawal of safe, effective products from the market and discourage further innovation in Europe. Moreover, potential inconsistencies between the Detergents Regulation and the EU Ecolabel criteria create confusion and regulatory overlap, which contradicts the Commission's objective of legislative simplification.
Our industry has proactively developed a comprehensive **risk assessment framework** for microbial cleaners. This framework, created through collaboration among European and U.S.-based detergent companies, provides clear guidance on evaluating microbial safety across various applications and formats, including sprays and food-contact surfaces. It promotes a holistic approach that considers both the **hazards** and **exposure** associated with microorganisms.

A.I.S.E. urges EU legislators to:

- ***Adopt a risk-based approach*** to microbial cleaners that evaluates both hazard and exposure.
- ***Build upon the industry-developed risk assessment framework*** to ensure only safe products reach the market.
- ***Align and streamline legislation*** across the Detergents Regulation and EU Ecolabel criteria to avoid duplication and conflicting requirements.

A coherent and science-based regulatory environment will support innovation, ensure product safety, and reinforce Europe's leadership in sustainable biotechnology.

Genetically Modified Organisms (GMOs)

The detergents and cleaning industry increasingly relies on biotechnology, including the use of genetically modified micro-organisms (GMMs), to develop products that are both effective and sustainable.

However, the existing EU legislative framework governing GMOs—particularly Directive 2009/41/EC on the contained use of GMMs and Directive 2001/18/EC on the deliberate release of GMOs—presents regulatory barriers to the development and deployment of these technologies, especially for our sector, when they are transposed at national level. Their national implementation has resulted in substantial administrative burdens, delays, and legal uncertainty.

A key example is the German Genetic Engineering Act (GenTG), which transposes both directives. Recent amendments to GenTG impose burdensome notification and registration procedures even for contained use at safety levels 1 and 2, delaying operations and increasing costs. Such fragmentation undermines cross-border research and market consistency within the EU.

The situation is further complicated by the inconsistent national application of the Nagoya Protocol on Access and Benefit Sharing. While the principle of equitable benefit sharing is sound, the lack of harmonised EU rules leads to legal uncertainty and significant administrative effort. In some cases, this has discouraged the use of foreign genetic materials altogether, limiting research and innovation potential.

These challenges hinder the detergents and cleaning sector's ability to contribute to scientific progress and environmental protection through the responsible use of biotechnology.

To unlock the full value of biotechnology, the Biotech Act should:

- **Harmonise the interpretation and application of GMO** legislation across Member States; A.I.S.E. encourages legislators to prioritize harmonizing laws across countries, particularly within Europe. This harmonization is crucial to ensure a consistent understanding and effort in handling genetic resources. Aligning national laws with the Nagoya Protocol will help create a unified legal framework that facilitates compliance and cooperation.
- **Simplify and accelerate** procedures for low-risk applications, particularly in contained use scenarios.
- **Clear, accessible guidelines** for accessing and using genetic resources, including benefit-sharing mechanisms.

A more coherent and efficient regulatory framework will enable our industry to innovate responsibly, contribute to the EU's sustainability goals, and maintain high safety standards for people and the environment.

Qualified Presumption of Safety (QPS) List

The current proposal to require that microorganisms used in detergents are listed on the **Qualified Presumption of Safety (QPS)** list maintained by the European Food Safety Authority (EFSA) is not appropriate for our sector. The QPS framework was originally developed for the **food and feed sectors**, including applications such as food additives, enzymes, and plant protection products. It does not reflect the specific needs, exposure scenarios, or safety considerations relevant to detergents and cleaning products.

Importantly, the QPS assessment process is **internally triggered by EFSA** upon receiving a market authorisation request for food or feed applications and it **cannot be initiated by applicants** for non-food uses, such as detergents. This makes it unfeasible for our industry to seek inclusion of safe microorganisms used exclusively in cleaning products.

Moreover, the QPS list focuses on a narrow set of criteria—such as taxonomic identity and antimicrobial resistance—without addressing critical factors for detergent applications, including:

- ***User exposure*** (e.g., dermal contact, inhalation, accidental ingestion);
- ***Potential allergenicity*** of microbial residues.
- ***Formulation-specific hazards*** and processing conditions.

Furthermore, in case of taxonomy changes, such changes are usually reflected with delay in the QPS, which might lead to problematic situations in terms of supply for the manufacturer.

Requiring exclusive use of QPS-listed microorganisms would severely limit the range of microbial cleaners available on the EU market and block the development of innovative, safe, and sustainable products.

A.I.S.E. strongly recommends removing the **QPS list requirement from both the Detergents Regulation and the EU Ecolabel criteria**. Instead, a tailored risk assessment approach—already developed by our industry—should be adopted. This approach considers the full safety profile of microbial cleaners in the context of their intended use, ensuring high safety standards while enabling innovation.

Conclusion

The proposed European Biotech Act represents a vital opportunity to modernise the EU's approach to biotechnology and to promote its full application across sectors that are central to the European Union's sustainability, competitiveness, and resilience goals. To succeed, the Act must avoid a narrow sectoral focus and instead embrace the wide array of industrial applications where biotechnology is already delivering meaningful benefits.

A.I.S.E. calls on the European Commission and EU co-legislators to adopt an **inclusive and forward-looking approach** that supports downstream sectors such as cleaning and detergents sector. By doing so, the EU can foster a regulatory environment that is science-based, risk-proportionate, and innovation-friendly.

A.I.S.E. remains committed to contribute constructively to the legislative process and sharing expertise to help shape an inclusive and effective regulatory environment for biotechnology in Europe.

About A.I.S.E.

A.I.S.E. represents the detergents and maintenance products industry in Europe. Based in Brussels, A.I.S.E. has been the voice of the industry to EU regulators since 1952. Membership consists of 30 national associations across Europe, 19 corporate members and 23 value chain partners. Through this extensive network, A.I.S.E. represents over 900 companies supplying household and professional cleaning products and services across Europe. Committed to promoting sustainable practices and innovation, A.I.S.E. collaborates closely with European institutions, industry stakeholders, and the public to enhance the sector's environmental protection, consumer safety, and regulatory compliance efforts.

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