# White Biotechnology Innovation Group: On the need for a new GMO legislation in Europe

## Introduction

The White Biotechnology Innovation Group[1] welcomes the European Green Deal. The Farm to Fork strategy is one important part of this ambitious initiative, aiming to accelerate the transition towards a sustainable food system that can adapt to, and mitigate, climate change while ensuring food security.

To meet these objectives, a range of solutions will be needed, including those originating from innovative biotechnology. Important contributors to innovation in this area are microorganisms (genetically modified or not), either used as products or as production organisms in contained use fermentation.

Already today, industrial biotechnology[2] is an important pillar of innovation in Europe, which contributes to a more resource-efficient, climate-neutral and knowledge-based economy that improves the health and well-being of people and the planet. The European Commission recognizes industrial biotechnology as a Key Enabling Technology, instrumental in modernizing European industry and driving the sustainable development of new and existing industries. It can also contribute to achieving the objectives of the new EU Industrial Strategy, in fields such as competitive sustainability and job creation.

To allow industrial biotechnology to play its role and secure its own competitiveness as well as that of its users, a significant modernization of the EU's GMO legislation (Directive 2001/18) is needed.

The Directive was designed in the late 1980s and last revised in 2001. There is now an urgent need for further revision:

- Its scientific approach focuses the evaluation and regulatory classification of organisms on the technologies used to develop them, rather than on the organisms' characteristics - an approach that seems outdated.
- Organisms obtained through post-2001 techniques are systematically subjected to an onerous regulatory approval process and to GM labelling requirements – even if they could have been developed using older techniques or resulted from spontaneous processes in nature.
- The current regulatory pathway does not effectively provide for timely authorizations to be granted.

We welcome the Commission's ongoing initiative to assess the role of post-2001 techniques (defined as "NGTs" – new genomic techniques) and their status under Union law. Access to state-of-the-art, efficient, accurate and safe tools and techniques is indeed essential to research and development in the white biotechnology sector.

To make best use of these tools, a science-based, proportionate and predictable regulatory approach to current and future biotech innovation is urgently needed if the EU wants to utilize contemporary scientific techniques at the same level as other regions, with the objective of bringing new, competitive and innovative solutions to the market.

[1] The White Biotechnology Innovation Group consists of companies active in the field of industrial biotechnology.

[2] Industrial/white biotechnology products and application areas include living microorganisms, as well as fermentation products. They are used in e.g. food, feed and agriculture.

## Policy asks

To this end, we call for a future-proof, science- and risk-based, operational legislation that is predictable and proportionate. This legislation shall be based on the characteristics of the organisms rather than on the technologies used to develop them.

In certain cases, similar organisms that cannot be distinguished from one another can be obtained through the application of different technologies. By regulating these organisms in an identical way, the legislation will be transparent, fair, and enforceable.

This future-proof, science and risk-based approach will instill confidence in the regulatory oversight system assuring safety for consumers and the environment.

This approach will foster innovation and competitiveness in Europe, and facilitate alignment with other legislations globally.

## Benefits and potential of gene technology / industrial biotechnology

Gene technology[3] (also known as modern biotechnology) provides ample opportunities to create new processes and products as well as to further develop and improve existing ones. The degree of understanding of microbial genomes, the ability to modify them with accuracy, the laboratory selection tools, and the characterization methods (e.g. sequencing) have tremendously improved over the past 10-20 years. These advances also led to an in-depth understanding of the genomic characteristics that are taken into account when performing risk assessments.

A few examples of the benefits of gene technology when applied to microorganisms:

- Microorganisms for agriculture: Agricultural crops depend on the soil microbiome (bacterial and fungal community). Introducing genetically engineered microbes into soil microbiomes could for instance improve nutrient or water uptake, with positive effects on stress tolerance. The benefits would be a more consistent yield of crops under challenging climate conditions without the need for additional use of mineral fertilizers or irrigation.
- Microorganisms for agriculture: crop protection against pests. The need for additional plant protection products is reduced.
- Microorganisms for animal health and nutrition: improving the utilization of feed, leading to less waste production, and improving the survival rate of the animals. The genetic basis for e.g. antibiotic resistance can be eliminated accurately and easily.
- Microorganisms for animal and human health: by e.g. impacting the gut microbiome in a positive way (probiotics).
- Microorganisms for food production: e.g. contributing to more efficient utilization of raw materials and reducing food waste.
- Microorganisms for fuel and chemical production based on renewables.
- Performance enzymes, which cannot be industrially produced using wild-type microorganisms, are readily produced by genetically improved microorganisms and used in a wide range of applications such as food production, animal nutrition, cleaning products, biofuels, textile manufacturing, bioplastic, etc.

[3] Gene Technology is a set of tools that allow targeted changes of the genome of an organism. Genome editing is a subset of the whole gene technology toolbox.

## Relevance to Green Deal objectives

As ambitious goals are set by the European Green Deal and the UN Sustainable Development Goals, there is also a need to prioritize and invest in innovative solutions, including in cutting-edge technologies, that can help achieve these.

Recognized as one of Europe's Key Enabling Technologies, industrial biotechnology helps deliver solutions to many current challenges, including more efficient resource use and contributing to good health and well-being. Industrial biotechnology uses enzymes and microorganisms to make bio-based products in a range of sectors. This helps reduce $CO_2$ emissions, provide sustainable alternatives to fossil-based products, and improve resource efficiency of industrial processes. Industrial biotech can also contribute to the delivery of probiotics, prebiotics, and micronutrients, and help meet the growing global demand for protein whilst reducing associated impacts on the environment.

All in all, industrial biotechnology plays a crucial role in addressing societal and economic challenges and supports the development of the bioeconomy. It stimulates job creation and sustainable growth. Proven benefits of industrial biotechnology for society and the planet include, but are not limited to:

- reduced use of raw materials, water, and energy.
- reduced waste production.
- reduced food waste.
- replacement of greenhouse gas emitting technologies with renewables.
- transformation of renewable raw materials into everyday products, providing an alternative to using fossil carbon sources.
- substitution of hazardous and fossil-based chemicals with bio-based alternatives.
- improved human and animal health, by applying 'safe by design' concepts.
- mitigation against climate change effects and improved land use in agriculture (using microorganisms).

The relevance of industrial biotechnology comes from the above multiple benefits and from the fact that it has been routinely used (as live microorganisms or fermentation products) for decades in food and feed production, agriculture, and many large industries, including cleaning products and biofuel production.

Burdensome regulatory procedures for products using gene technology in industrial biotechnology in the EU, however, prevents innovative products from entering the market. At the same time in other parts of the world, products obtained with e.g. genome editing that could also have been obtained with non-GM techniques are not seen as different from their conventional counterparts.

Therefore, it is important that the EU green transition includes a reform towards a science-based, proportionate, and predictable regulatory approach to current and future biotechnology innovation. This would help EU researchers regain lost ground in fostering the role of innovative bio-based solutions for sustainable agriculture, food production, and as part of the circular bioeconomy. At the same time, empowering the EU industry to further increase innovation, including by NGTs, would provide direct benefits to the EU in the form of competitive solutions for sustainable growth.

## White Biotechnology Innovation Group

The White Biotechnology Innovation Group consists of the following companies active in the field of industrial biotechnology: AB Enzymes; Adisseo; Ajinomoto; Amano Enzyme; BASF; Bioseutica; Biomin; Chr. Hansen; Clariant; CJ Europe; C-Lecta; Corbion; CSK Food; DSM; Dupont; Evonik; Huvepharma; Kerry; Lallemand; Lesaffre; NHU Europe; Novozymes; Nutreco; ORFFA; Pintaluba; Puratos; Volac and WeissBioTech.