Summary – Position paper on amending the European GMO legal framework for microorganisms

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1. Summary

The current EU regulations governing genetically modified organisms (GMOs) and, in particular, genetically modified microorganisms (GMMs) pose major challenges for companies seeking approval for innovative products and production processes. New genomic techniques (NGT), such as the Nobel Prize-winning CRISPR/Cas technology, offer enormous potential for biotechnology as a key technology for a future-oriented, climate-neutral and sustainable economy. Our position paper describes an evidence- and knowledge-based proposal for redesigning the EU GMO legal framework for microorganisms. The central demand is to move away from the current process-based GMO legal framework towards a product-based one.

2. Background and motivation

Genetically modified microorganisms (GMMs) are of central importance to modern industrial biotechnology. These microorganisms produce a wide range of fermentation products or are themselves the product. Access to state-of-the-art, efficient, precise and safe genetic engineering tools is crucial in this context. In order to make optimal use of these tools, a scientifically sound, proportionate and reliable regulatory approach for current and future biotechnological innovations is urgently needed – especially if the EU wants to remain competitive and retain its existing innovation potential.

3. Challenges of the current legal framework

The current EU legal framework is based on the manufacturing process used (of a GMM) rather than on the characteristics of the end product (fermentation product or GMM). This process-based approach, which was developed in the 1980s and 1990s, is outdated and no longer reflects the state of science and technology. This creates significant barriers to innovation and market access.

The existing process-based system leads to regulatory uncertainty for companies and authorities, as different authorisation requirements apply to identical products with different manufacturing processes. The lengthy (often more than five years) and cost-intensive authorisation procedures inhibit the development and market launch of new biotechnological products. This process-based regulation in the EU puts European and German biotechnology at a disadvantage in international competition, as many other countries apply product-oriented regulations. This means that opportunities for the use of advanced biotechnologies that could contribute to achieving climate, resource and food security goals are being missed.

4. Proposed solution: product-based regulatory approach

The position paper recommends a fundamental shift from a process-based to a product-based legal framework for GMMs in the EU. The focus is on assessing the properties and safety of the commercial product, regardless of the genetic modification tools used.

A three-tier categorisation system for microorganisms is proposed (see figure below): Category 0 comprises wild-type strains or conventionally mutated strains that do not require GMO regulation. Category 1 (cisgenetics) includes genetically modified strains without foreign DNA, which are treated like Category 0, but must be reported as a product when placed on the market and entered in a register. Category 2 (transgenics) comprises strains with foreign DNA which, if the microorganism is part of the end product, are subject to GMO regulation and labelling requirements. For all categories, a scientifically sound, risk-based safety assessment by the manufacturers in accordance with current standards is mandatory. Changes to already approved production strains will in future be regulated by a simplified notification procedure and no longer by a complete re-approval procedure.

5. Findings from the case studies

The case studies presented in the position paper show that the current process-based system leads to regulatory and economic hurdles. It prevents the market launch of sustainable products such as reduced-alcohol beverages or improved probiotics and causes delays and additional costs when updating production strains. In addition, legal uncertainty arises for products where the origin of the genetic modification cannot be clearly verified by the regulatory authorities in the commercial product. A product-based approach solves these problems by focusing on the safety and characteristics of the commercial product rather than the method of its production.

6. Advantages of a product-based regulatory approach

The introduction of a product-based regulatory framework strengthens the competitiveness of European and German biotechnology companies by removing unnecessary regulatory hurdles and speeding up approvals. This allows innovations to be developed and brought to market more quickly, which promotes the development of sustainable biotechnological products and processes. Biotechnology can thus be used as a key technology for a circular, resource-efficient and climate-neutral economy. At the same time, safe, innovative solutions for food and feed production are promoted and food security is strengthened. Overall, the German biotechnology sector will grow, create high-quality jobs and open up new economic opportunities.

The EU can be an international pioneer with the innovative, forward-looking regulatory concept for microorganisms that has been presented. The proposed regulatory concept reflects international basic principles very well, and also includes methods that will be developed in the future. By focusing on the commercial product and the origin of the sequence (foreign/own DNA) as decisive parameters for the authorisation requirement, the aim is to achieve a simple and easily comprehensible categorisation that can also be checked quickly and easily by the competent control authorities.

7. Conclusion

A modern, product-based regulatory framework for genetically modified microorganisms is crucial if the EU and Germany are to maintain their leading role in industrial biotechnology, achieve sustainability goals and secure economic growth. The recommendations in this position paper offer a clear and actionable path forward.

Proposal for the gradual categorisation of microorganisms