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Agrifood biotechnology in Flanders:

regulatory areas where our industry needs most help to excel

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Summary

Agrifood (bio)technology is key to tackling global challenges like population growth and sustainable food supply. The Flanders region in Belgium has a strong agrifood ecosystem, contributing to the EC Initiative for Boosting Biotechnology and Biomanufacturing in the EU and the Farm to Fork strategy. This paper by flanders.bio urges EU legislators for regulatory support in four key areas of EU legislation:

1. **New Genomic Techniques (NGTs)**: Separate NGT regulation from patent law and modernize the GMO framework across sectors to be in line with existing scientific advances, including microorganisms.
2. **Biocontrol products**: Define biocontrol products, prioritize or fast-track the approval of active ingredients and the authorization of biocontrol products, and enable an environment that promotes innovation.
3. **Microbial plant biostimulants**: Adopt a criteria-based approach instead of a positive list to establish standardized regulations for microbial plant biostimulants.
4. **Novel foods**: Allow pre-approval tastings of novel foods and adopt best practices from The Netherlands' Code of Practice and/or UK's Regulatory Innovation Office.

These recommendations aim to enhance Flanders' role in advancing EU agrifood biotechnology.

Disclaimer

The study and this resulting document were prepared by flanders.bio and its AgriFoodTech Flanders working group, with support of its wider membership and network of experts. Views and information expressed in this document do not necessarily reflect the opinions of any single member or their organization.

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Agrifood biotechnology for Flanders' growth

Introduction and objectives

In its recent **Biotechnology and Biomanufacturing Initiative**, the European Commission has underscored the critical role of agrifood biotechnology in addressing pressing global challenges, including the growing world population and the resulting increase in demand for raw materials, energy, and arable land (1). In addition, in April 2024 the European Parliament included biotechnology as a Net-Zero Technology in the Net-Zero Industry Act (2). In this context, **flanders.bio** – an independent cluster organization in Flanders supporting the medical and agrifood biotechnology sectors – seeks to highlight the unique potential and strengths of the Flanders region in Belgium, showcasing how its innovative agriculture, food and industrial biotechnology ecosystem is well-positioned to contribute to the European objectives outlined in the EC Initiative for Boosting Biotechnology and Biomanufacturing in the EU, the Farm to Fork strategy and the Net-Zero Industry Act.

In this policy paper, flanders.bio aims to provide valuable input to the European Commission and the EU legislators on agrifood biotechnology solutions, rapid scientific advancements, and the areas where the industry needs the most help to excel. By identifying key areas where support is needed, we intend to inform the Commission's approach, provide specific recommendations and ensure that our region's capabilities are fully leveraged in shaping the EU future.

Overview of the sector in Flanders

Agrifood innovation and biotechnology are intrinsically linked, driving significant advancements in the agriculture and food sectors. Over the past four decades, Flanders has cultivated a thriving agrifood ecosystem, comprised of numerous companies, research institutions, and organizations working collaboratively. The region's robust scientific R&D infrastructure and expertise have proven to be crucial for fostering a favourable environment for these (bio)technological innovations. In addition, cutting-edge research is seamlessly translated into societal and economic benefits through a proactive technology transfer process (3). This dynamic ecosystem, outlined in ANNEX 1: Ecosystem description of agrifood in Flanders of this document, serves as a foundation for our informed messages and recommendations toward the European Commission and the EU legislators.

Biotech for agriculture & food security: our recommendations

Our messages and recommendations focus on specific legislative and regulatory areas where urgent support and actions are needed. Our recommendations directly address the bottlenecks and opportunities outlined in the EC Initiative for Boosting Biotechnology and Biomanufacturing in the EU document (1).

We hereby underscore the importance of advancing the legislative proposal on **New Genomic Techniques (NGTs)**, the inclusion of **biocontrol products in Regulation (EC) No 1107/2009**, the expansion of the use of **microorganisms as biostimulants in Regulation (EU) No 2019/1009**, and an enabling regulatory landscape for **novel foods**. These areas, all contributing to environmental sustainability and resilient food systems, stand to benefit from streamlined and enabling regulatory pathways. However, the reality today is far from the objective with progress impeded by inadequate regulation and/or lengthy and burdensome authorization procedures.

For more detailed information, please refer to ANNEX 2: New Genomic Techniques, ANNEX 3: Biocontrol products, ANNEX 4: Microbial biostimulants, and ANNEX 5: Novel foods.

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1. Legislative proposal on New Genomic Techniques

As advocates for a growing and innovative biotechnology ecosystem in Flanders and Belgium, we support the European Commission's legislative proposal on New Genomic Techniques and the European Parliament's vote in favour (4). However, we remain cautious due to ongoing discussions at the EU member state level concerning among others the proposed patenting ban for all "NGT plants, plant material, parts thereof, genetic information and process characteristics" (5).

In addition, we call for an overall modernization of the EU GMO framework – covering Directives 2001/18/EC and 2009/41/EC, as well as Regulation (EC) No 1829/2003 – beyond the scope of the NGT proposal. This revision across all sectors must extend to include the application of NGTs to microorganisms (GMMs), ensuring alignment with current scientific and technological advancements and improving Europe's global competitiveness. More details can be found in ANNEX 2: New Genomic Techniques.

- **Key messages**:
  i. If enabled, NGT-derived plants have the potential to significantly contribute to the European climate objectives by introducing climate-resilient crops and reducing the environmental impact of farming practices. In addition, they are potential biological factories of high-value molecules, such as therapeutic proteins.
  ii. NGT regulation and patent law represent two distinct and complex issues that should not be conflated. The proposed regulatory framework for NGTs, the protection of inventions and the patentability of plants are separate matters, each requiring careful consideration.
  iii. The European Food Safety Authority (EFSA) has recently published its Scientific Opinion on the application of New Genomic Techniques to microorganisms (6). With flanders.bio, we here highlight and fully support the key findings from this report:
    1. NGTs do not introduce novel hazards or risks compared to established biotechnology methods for microorganisms.
    2. NGTs offer advantages such as greater efficiency, specificity, and predictability in genomic modifications for microorganisms.

- **Recommendations**:
  i. Conduct a thorough study on NGT patent rights: it is premature to hastily impose restrictions on the patentability of NGT plants. The role of intellectual property (IP) protection in the plant domain, encompassing both Plant Breeder's Rights and patent rights, necessitates a thorough analysis and a nuanced debate. The Commission's commitment to conducting a study on this matter is commendable, and the outcomes should precede any debate or conclusive decision. However, it is essential that this study does not delay ongoing discussions in the meantime.

  ii. We endorse the policy requests and recommendations from EuropaBio with regards to GMMs, summarised as follows (7):
    1. Include in the NGT legislation a commitment for the EC to publish a proposal for additional policy actions on GMMs.

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2. Accelerate the overall revision of the GMO framework beyond plants to be in line with existing scientific advances in all relevant sectors. Ensure that any modernizations to GMM-related legislation, including the Contained Use Directive 2009/41, are included in this process.
3. Base legislation on the characteristics of the organisms (or their products) rather than on the techniques used to develop them. Europe needs a future-proof, product-centric regulatory framework for biotechnology products with regulatory requirements proportionate to safety risk.

2. Advancements for biocontrol products

We aim to raise awareness on current regulatory barriers in Regulation (EC) No 1107/2009 on Plant Protection Products, that hinder investment in and development of biocontrol products for crop protection. These products include microbials, natural substances, proteins, semiochemicals, bacteriophages, and RNA interference (RNAi). The barriers imposed by this regulation are acknowledged in the EC Initiative for Boosting Biotechnology and Biomanufacturing in the EU and negatively impact the commercialization of biocontrol products across Europe.

- **Key messages**:
  i. The EU has by far the longest biocontrol registration timelines globally. While registration in the EU takes 6-10 years in practice, other countries typically complete the process in just 2-3 years (8).
  ii. Prioritizing or fast-tracking the approval of biocontrol products will help reduce chemical pesticide use, aligning with the EU Green Deal's pesticide reduction targets and supporting the transition from "lab to field".
  iii. While the inclusion of biocontrol products under Regulation (EC) No 1107/2009 offers a short-term solution, it is not future-proof. Given the fundamental differences between biocontrol products and chemical plant protection products, we advocate for a dedicated regulatory framework specifically tailored to biocontrol products, beyond the scope of Regulation (EC) No 1107/2009.

- **Recommendations**: we support the recommendations from initiatives like **Plants for the Future ETP** (9) and the **International Biocontrol Manufacturers Association** (IBMA) (10), including:
  i. Define biocontrol products: establish a clear definition for biocontrol products, reflecting the range of products available, to ensure regulatory alignment across all Member States.

  ii. Streamline registration (approval and authorization) processes:
    1. Allow greater science-based flexibility in the assessment process for biocontrol products.
    2. Implement prioritization or fast-track procedures for biocontrol products and reduce administrative burdens.
    3. Strictly implement certain articles in Regulation (EC) No 1107/2009 such as the process of Mutual Recognition according to Art. 40.

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4. Increase the predictability of the timing of the registration process by respecting the legal deadlines.
5. Set reasonable application fees in accordance with the complexity of the presented registration dossiers and the time needed for evaluation.
6. Review the need for a new biocontrol products legislation, a dedicated regulatory framework specifically tailored to biocontrol products.

3. Advancements for microbial biostimulants

In July of 2022, the EU formally recognized plant biostimulants by implementing the Fertilizing Products Regulation (FPR, (EU) 2019/1009) across all 27 EU member states, establishing clear safety and quality standards (11). However, challenges remain that must be addressed for the plant biostimulants sector to truly flourish within a unified European market.

- **Key message**: Component Material Category (CMC) 7 of the FPR currently permits only four types of microorganisms in microbial plant biostimulants. This limited positive list supports the maintenance of distinct national regulations on fertilizing products, making access to the EU market for other microbial plant biostimulants of lower priority.

- **Recommendation**: we endorse the recommendations of the **European Biostimulants Industry Council** (EBIC), specifically:
    i. Adopt a criteria-based approach: the restricted positive list under CMC 7 excludes many microorganisms already used under national legislation in microbial plant biostimulants, or still under research. A criteria-based approach should be introduced to establish standardized regulations, enabling broader access to the EU market for microbial plant biostimulants.

4. Tasting of novel foods

"*Novel food*" refers to any food that was not significantly consumed in the EU before May 15, 1997. Regulation (EU) 2015/2283 establishes the legal framework for their authorization and use, with EFSA responsible for scientific assessments to ensure their safety for consumers. However, this regulatory framework is often criticized for being slow and cumbersome because of **"stop-the-clock"** procedures, where the timeline is paused when additional information or clarifications from the applicant are required. In addition, to promote product development, market entry, and consumer acceptance of biotechnology-based novel foods, we propose to address other regulatory barriers like pre-approval tasting to support innovation.

- **Key message**: streamline the novel foods authorization procedures and extend pre-approval tasting capabilities to all European member states. This is crucial to advance innovation in novel foods. For example, the definition of procedures could facilitate the acceptance and market entry of novel foods, including innovations like fermentation-derived protein.

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- **Recommendations**:
  i. Improve transparency and enable proactive dialogue between applicants and EFSA: introduce mechanisms for preliminary consultations to review dossiers pre-submission, reducing incomplete applications and subsequent delays.

  ii. Implement regulatory sandboxes for tastings: integrate novel foods into the Initiative's proposed regulatory sandboxes, allowing controlled experimental tasting sessions before seeking EU Novel Food approval from EFSA. This permits the collection of consumer feedback and refinement of products under limited conditions and in a controlled environment.

  iii. Learn from international and national examples: study and potentially replicate successful practices from countries like Singapore, Israel, and the US, which allow tasting of cell-based prototypes. Also recently, in 2023, The Netherlands introduced its own 'Code of Practice', allowing Dutch companies to request an official tasting panel limited to cultivated meat, making it the first and only country in the European Union to enable pre-approval tastings (12). In addition, on the 8th of October 2024, the United Kingdom (UK) government announced that it is creating Europe's first regulatory sandbox (a Regulatory Innovation Office) for cultivated proteins and foods to improve the Food Standards Agency's knowledge in this area and to speed up approvals for biotechnology. This initiative comes with £1.6 million in public funding (13). We encourage the Commission to look to the Netherlands' Code of Practice and the UK's Regulatory Innovation Office as models for enabling pre-approval tastings across the EU.

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ANNEX 1: Ecosystem description of agrifood in Flanders

Important disclaimer

The following ecosystem description provides an overview of the agriculture, food, and industrial biotechnology ecosystem in Flanders, based on currently available data and insights. While comprehensive, it may not encompass every detail of this fast-evolving landscape. This overview serves as a foundation for future updates as the ecosystem evolves. Input is welcome at info@flanders.bio.

Introduction to flanders.bio

Flanders.bio is a dynamic, member driven organization with currently more than 340 members from Belgium and abroad. We help our members to create value by organizing networking and training activities, supporting internationalization, providing services, and building expertise. Flanders.bio and its members are proud advocates of a reputable global-impact ecosystem in life sciences. Flanders.bio is supported by a number of strategic partners including VIB, Johnson & Johnson, PwC, KBC Securities, Akkodis, BioLizard, PMV, IQVIA, Select and QBD Group. More information on https://flanders.bio.

Flanders: a major European R&D hub in plant or 'green' biotechnology

The Flemish biotech sector is globally renowned not only for its leadership in life sciences and medical biotechnology, but also for its groundbreaking contributions in plant and industrial biotechnology. Over the past 40 years, pioneering researchers and innovators in Flanders have made discoveries that are now integral to agriculture, food, and other industries worldwide. The remarkable ascent of Flanders as a global leader is beautifully captured in the book *Biotech in Flanders: A Stunning Story*, authored by Jo Bury, Johan Cardoen, and Dirk Reyn (3). In the following sections, we provide an overview of current key contributors in the Flemish agrifood ecosystem.

Flanders' successful ecosystem

Plant or "green" biotechnology is one of Flanders' long-standing strong suits. Over the past four decades, the region has made tremendous strides, driven by pioneers such as Marc Van Montagu, Jeff Shell, and Dirk Inzé. Their groundbreaking work in plant genetics and biotechnology at the Flemish Institute for Biotechnology (VIB) laid the foundation for modern crop advancements. Companies like Plant Genetic Systems (acquired by Bayer), Devgen (acquired by Syngenta), and CropDesign (acquired by BASF) have emerged from this innovative environment, giving ground to a successful ecosystem (3).

- Currently, the Flemish ecosystem comprises spinoffs from Flemish research institutes including Biotalys, Aphea.Bio and Protealis, established companies including Inari, BioFirst Group, DCM and Globachem, and multinational corporations such as Bayer, Syngenta and BASF.

- Various Flemish universities – such as UGent, KU Leuven and UHasselt – have specialized education and research tracks relevant to agrifood. Prominent examples are UGent's CropFit, VIB's Plant Systems Biology (PSB), the KU Leuven Plant Institute (LPI), and UHasselt's Centre for Environmental Sciences (CMK).

- Research institutes like VIB, ILVO, VITO, Scientia Terrae, and plant practical research centers (e.g. pcfruit, PSKW, Viaverda, Research Centre Hoogstraten, Praktijkpunt Landbouw, and Inagro) are integral to Flanders' agrifood landscape. They bridge the gap between scientific discoveries and practical applications, ensuring that innovative solutions can reach farmers and consumers on a commercial scale. In addition, the translation of knowledge into societal

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and economic impact is achieved through a professional process of proactive technology and knowledge transfer.

- A standout initiative within the ecosystem is **Biotope** by VIB, an incubator program designed to support biotech startup teams. Biotope helps transform groundbreaking agrifood innovations into investment-ready businesses by offering tailored incubation services, access to state-of-the-art facilities, and guidance from leading experts in biotechnology and entrepreneurship.

This biotechnology ecosystem is supported by a.o. flanders.bio, the initiator and driving force behind this overview. Additionally, **Flanders' FOOD**, the spearhead cluster for agrifood in Flanders, plays a pivotal role in implementing the Flemish research and innovation strategy. With approximately 300 company members, Flanders' FOOD supports and stimulates the Flemish agrifood industry by fostering innovation projects and creating a "trust zone" for open collaboration among stakeholders. Their thematic program *New & Shifting Resources* is particularly aligned with advancing biotechnology applications in the food industry.

Flanders' fields of expertise

By 2050, the global population is expected to approach ten billion people, creating a heightened demand for diverse foods with less arable land, fewer resources, and in more extreme climates. To meet this global demand, farmers will need to have access to a range of innovative tools, including biocontrol products, biostimulants, and advanced crop breeding techniques. Genome editing (or NGT's in the EU-language) will also play a pivotal role, facilitating the efficient development of desired traits in crops. However, sustainable crop protection and the creation of new crop varieties alone will not suffice; smart and precision farming solutions are equally essential. Fortunately, Flanders is at the forefront of all these scientific and technological advancements.

1. *Biocontrol products and biostimulants*

Biocontrol products are alternatives to chemicals to control plant pests and diseases effectively and sustainably, offering a solution to fill the gap in a farmer's toolbox (14). Flemish companies are at the forefront of developing these innovative solutions, with the goal to reduce the use of harmful chemical plant protection products and enhance biodiversity. For instance:

- A large number of microorganisms that coexist with plants haven't been isolated and identified so far. **Aphea.Bio** aims to exploit this untapped microbial space, leveraging plant microbiome dynamics to pioneer the development of novel microbial biostimulant and biocontrol products. Respectively to reduce fertilizer use and manage crop diseases sustainably. In 2023, the company secured 70 million EUR Series C funding, supporting its rapid growth (15).

- Flanders-based **Biotalys** is developing novel protein-based biocontrol solutions. Leveraging their Ilama antibody-based technology (successful in the pharmaceutical sector thanks to Flemish Ablynx, now part of Sanofi), the company introduces its AGROBODY™ platform. This platform generates novel biocontrols as effective alternatives to chemical plant protection products. In 2021, Biotalys was listed on Euronext Brussels (16).

- **BioFirst Group** comprises of four core brands. Among these, Biobest specializes in pollination and biocontrol products for horticulture, while Biotrop leads in biological control solutions for open-field farming. The company reported sales figures up to 500 million EUR, of which 80% are non-EU sales *(Panel discussion, Knowledge for Growth, May 2024)*. Their biocontrol products face challenges in reaching European farmers due to the cumbersome European authorization processes.

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- DCM (De Ceuster Meststoffen nv), a leading family-owned Flemish company, specializes in sustainable biocontrol products and fertilizing materials designed to support eco-friendly agriculture. Focusing on innovative biocontrol solutions such as PMV®-01 and the bacteriophage-based Phact® platform, DCM offers effective natural alternatives to chemical pesticides, enhancing crop resilience and reducing environmental impact. Committed to sustainable agriculture, DCM also develops innovative biostimulants and fertilizers that reduce dependency on chemical pesticides and promote soil health.

Other notable producers and R&D startups in the Flemish ecosystem, including Globachem, Bi-PA, Janssen PMP, Koppert, Certis Belchim, Compo, Lima Europe, Aphasol, Syngenta, BASF, Bayer, and emerging companies like Zymofix, B-Cos and Landman.Bio are actively expanding the biocontrol and biostimulant market, further driving innovation and growth in the sector.

In addition, pioneering efforts extend beyond innovative companies to include Flemish universities and research institutes. At the KU Leuven Plant Institute for example, researchers study plants' natural predators and the intricate dynamics of the plant microbiome. They focus on opportunities of RNAi, bacteriophages (in collaboration with ILVO), and natural antimicrobial compounds to enhance systemic plant resistance, akin to *'plant vaccination'*. At UHasselt (CMK) and UGent (CropFit), researchers are exploring natural resources like biological by-products and plant residues to develop plant-based biocontrol and biostimulant products. In addition, CMK recently secured EFRO funding to establish rapid assessment climate chambers, allowing precise short-term testing of ecosystem responses, crucial for assessing biodiversity, soil health, and nutrient cycles. These units are available for companies interested to test for example new biocontrol products and biostimulants. And research institute Scientia Terrae developed the DNA Multiscan in 2004, a fast diagnostic for common fungal and bacterial infections in crops. It further researches and develops new biostimulants, new compositions and formulations for organic fertilizer, and alternatives for peat in substrates.

2. *Crop breeding*

Crop breeding involves the deliberate crossing of well-chosen genotypes and the selection through several steps of improved varieties with desired characteristics. These traits can include higher yields, disease resistance, enhanced appearance, as well as improved nutritional content and tolerance to environmental stresses such as drought or heat (17). This expertise stands as a necessary tool in addressing the imperative highlighted in the Farm to Fork strategy: the urgent shift towards more plant-based diets and alternative protein sources. Aiming to promote healthier diets through the consumption of nutrient-rich, locally sourced, and sustainably produced foods.

- ILVO has a history of almost 100 years in plant breeding and in breeding research. The result of these breeding activities are new plant varieties of different plant species such as forage crops (e.g. grasses, clovers and Plantago), cover crops (e.g. mustard), protein crops (quinoa, chickpea) and ornamentals. Through bi-lateral collaborations, the institute supports also the breeding activities of smaller companies with low investments in R&D, mostly in the ornamental sector. In recent years, dedicated open-access on-field phenotyping infrastructure (HYDRAS) has been installed to enable the development of climate-resilient crops and testing specific management practices, including the effect of the application of biostimulants. Specifically for protein crops, ILVO initiated in 2013 a breeding program in soybean, with the purpose to select varieties adapted to local cultivation in North-West Europe. This would contribute to reduce the need to import of soybean products, and consequently reduce the negative environmental impact of soybean cultivation in South America. This breeding

program and the developed breeding tools, in combination with knowhow contributed by VIB to identify locally adapted *Rhizobium* bacteria and inoculation technology, formed the basis of Protealis, a company focused on developing high-yield, protein crops suitable for European farming. The company aims to reduce Europe's dependency on protein imports by enabling and promoting sustainable, locally grown protein crops. In January 2024, the company announced the successful closing of its Series B funding round with 22 Million EUR (18). ILVO keeps on exploring the potential in Flanders of other protein crops. Current breeding efforts in this area focus on quinoa and chickpea. In parallel, the institute works on the development of the value chain for these innovative crops through investments in pilot infrastructure for seed cleaning and pre-processing.

Other examples in the Flemish ecosystem include:

- SESVanderHave, a global leader in sugar beet seed production. The company focuses on developing sugar beet varieties that offer higher yields, better disease resistance, and enhanced tolerance to environmental stresses. Their innovations ensure that sugar beet remains a viable crop for European farmers.

- Better3Fruit, a spinoff company of KULeuven established in 2005, is one of the major apple and pear breeders worldwide. The company develops new apple and pear varieties that are grown and marketed under their own brand globally. An important aspect on which they are focusing is meiotic crossing-over to stack the right combination of traits in one pome fruit variety. Moreover, research of the KU Leuven Plant Institute forms the basis for the discovery and implementation of novel breeding technologies (De Storme Lab).

3. Genome editing

By precisely targeting specific genes, genome editing (or NGTs in the EU-language) can be used to introduce improvements in plant varieties that better address global challenges, surpassing the speed of earlier breeding methods (19).

Flanders stands ready for this agricultural innovation, backed by talent, investments, and a great pioneering history. Inari, an American company with its R&D center in Flanders since 2019, leads in genome editing for climate-resilient seeds. Their goal: enhance yields, conserve resources, and reduce environmental impact. The genome editing field has been enabled by CRISPR and related technologies. Leveraging these, they pioneer maize and soy improvements, with plans for wider crop expansion. These CRISPR advancements, alongside progress in biotechnology - which has been accelerated by improvements in DNA synthesis and assembly technologies-, propel genome editing. This is evidenced by VIB's drought resistant maize or BASF's Ghent Innovation Centre research on adapting wheat varieties for stable yield in adverse climatic conditions, vital for global food supply.

4. Precision farming, smart farming and farm automation innovation

Flemish strategic research centres like ILVO, imec, VITO and Flanders Make as well as the KU Leuven Plant Institute drive a diverse range of solutions, from soil to weather monitoring, plant sensor technology, employing satellites and drones for variable rate irrigation, targeted spraying, and fertilization, vertical farming, multi-and hyperspectral imaging technologies. Automated vehicles and harvesting robots streamline operations, while sensor technology and data processing yield customized insights. Various platforms, including tractors and drones, deploy sensors to map field variability, generating vast datasets. Algorithms, such as artificial intelligence (AI) and machine learning, extract actionable information for site-specific tillage and product application, optimizing resource usage based on crop and soil needs.

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Robovision contributes by developing advanced AI-driven platforms that enhance the analysis of agricultural data, enabling more precise decision-making in farming operations. Urban Crop Solutions specializes in vertical farming technology, offering innovative indoor farming systems that maximize space and resource efficiency, making agriculture possible in urban environments. Colruyt Group is actively involved in sustainable farming initiatives, integrating smart farming technologies into its supply chain to improve efficiency and reduce environmental impact.

5. *Pyrolysis and biochar*

Together with ILVO, UHasselt's CMK is at the forefront of developing and evaluating biochar as a sustainable solution in agriculture and environmental management. Biochar, a carbon-rich product derived from the pyrolysis of biological residues, holds significant promise for improving soil health, reducing climate impact, and valorising agricultural waste by converting residual biomass into biochar for use in sustainable horticulture.

This research focuses on tailored applications of biochar, including enhancing soil fertility in drought-sensitive, low-carbon, or contaminated soils, and serving as a sustainable alternative to peat in soilless cultivation systems. UHasselt's state-of-the-art ECOTRON facility is utilized to assess the resilience of biochar under future climate scenarios, showcasing its comprehensive expertise in developing innovative agricultural practices that are both sustainable and climate-resilient.

Flanders: bringing extensive industrial and food biotechnology know-how

Sustainably scaling up

Industrial biotechnology, also known as "white biotechnology", is a major innovation driver in Flanders' agrifood sector. This technology uses natural systems, like microorganisms (through microbial fermentation) and enzymes (in biocatalysis), to produce valuable compounds and biomass on a large scale. Compounds include among others vitamins, proteins, carbohydrates, and specialty chemicals (20). They are typically more environmentally friendly than those produced through traditional chemical methods or animal-based processes, as industrial biotechnology greatly supports a circular economy, where resources are reused and recycled rather than discarded (21).

Flanders' fields of expertise

1. *Precision fermentation*

In industrial biotechnology, precision fermentation leverages microbial cells who are engineered to produce specific compounds through optimization of their native gene pathways or the establishment of new ones. Using synthetic biology techniques, these microorganisms are transformed into highly efficient production machines, so-called "**cell factories"**, capable of increased (1) production of endogenous metabolites, (2) production of heterologous compounds or (3) *de novo* synthesis of new compounds (20). Following fermentation, the desired compounds can be recovered from the cells or the fermentation medium through downstream processing. The Flanders region hosts several leading companies and innovators in this field.

- In 1995, Genencor, a pioneer in industrial biotechnology, began operations in Flanders as Genencor International BV. After DuPont acquired Genencor in 2011, the site's biotech role grew. In 2021, IFF (International Flavors & Fragrances) merged with DuPont's Nutrition & Biosciences devision, bringing Genencor under the IFF brand. Today, the facility continues its work in biotechnology, specializing in enzyme production for industries like brewing, baking, animal feed, biofuels, textiles, and detergents.

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- As a global leader in the bakery, patisserie, and chocolate sectors, **Puratos** has been innovating in food enzymes through precision fermentation since 1994. Their expertise contributes significantly to improving quality, shelf life, and nutritional profile of baked goods. The group also has its own corporate ventures arm, **Sparkalis**, to complement the company's innovation portfolio and accelerate business growth in the food tech ecosystem.

- With a substantial presence in Flanders, **Cargill** operates specialized R&D centers focused on biotechnological advancements, including precision fermentation for producing sweeteners, texturizers, and proteins. Their partnership with **Enough** in the Sas van Gent (NL) harbor is a prime example of their commitment to sustainable food innovation (22).

- **AB InBev**'s Global Innovation and Technology Centre (GITEC) in Leuven drives their advancements in brewing and packaging. As fermentation experts, their innovation focus extends beyond traditional brewing to include side stream valorization and precision fermentation, respectively represented by their Evergrain and BioBrew initiatives.

- Specializing in precision fermentation, **Inbiose** produces specialty carbohydrates like human-milk oligosaccharides (HMOs) for infant nutrition, dietary supplements, and functional foods. Their work contributes to the global demand for health-enhancing ingredients. In 2021, the scale-up secured 15 million EUR funding from the European Investment Bank (23). The company meanwhile received regulatory approval for several of its HMOs, including for 2-fucosyllactose in China.

- **AmphiStar**, in contrast, employs precision fermentation technology to develop sophorolipid biosurfactants that are entirely derived from biobased waste and side streams. The biosurfactants have diverse applications, including home care, personal care, cosmetics, agrochemicals, and many more. In April 2024, the startup announced it had secured 6 million EUR in Seed funding (24).

- **NovelYeast** researches the many industrial applications of yeast. They also provide R&D services for the utilization of yeast as a tool in industrial biotechnology. A major focus of the company is the development and commercial implementation of superior industrial yeast strains and associated industrial processes for the production of biofuels, bio-based chemicals, specialty sugars, single-cell protein, alcoholic beverages, nutraceuticals, probiotics, and specialty proteins.

Alongside food ingredients and biomaterials, the demand for animal-free protein alternatives is growing to support global protein needs. **The ProteInn Club**, a collaboration between Bio Base Europe Pilot Plant, Ghent University, CAPTURE, and ILVO, supports this protein transition by connecting and guiding stakeholders across the alternative protein value chain. Innovative Flanders-based startups lead in precision fermentation for animal-free protein production:

- **Those Vegan Cowboys** produces casein, a key protein traditionally derived from cow's milk, through precisely engineering yeast. Casein is crucial in cheese production as it coagulates to form curds when rennet or acid is added. The animal-free casein developed by the company can be used to create cheese with taste, texture, and nutritional qualities similar to traditional dairy cheese. In March 2024, Those Vegan Cowboys announced a partnership with Formo, a Germany based scale-up also pioneering bio-identical casein through precision fermentation. Together, they have assembled a team of over 60 scientists to advance their R&D efforts (25).

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- Paleo's science team specializes in the production of myoglobin, in nature found in the muscle tissue of animals, via precision fermentation. The protein is crucial for imparting the taste, flavour, and appearance of meat in plant-based alternatives. In September 2023, the company raised 12 million EUR in Series A funding (26).

- Biolynx focuses on research and development of new processes and products from fungi and microfungi. One of their main focuses is the development of new meat alternatives. However, the company also works on other (micro)fungi-projects.

2. Biomass fermentation and cultured meat

Producing food products with microbial cells or animal cell cultures rather than directly from plants or animals, is emerging as a transformative field in Flanders (27). Thanks to ongoing advancements in industrial biotechnology, material sciences, and bioprocess engineering, companies in this sector are pioneering new ways to produce sustainable products through advanced technologies.

Biomass fermentation

Biomass fermentation focuses on the large-scale cultivation or 'brewing' of microbial cells such as bacteria, yeast, microalgae, or fungi to produce biomass rich in proteins - often referred to as **single-cell protein** -, fats, and other nutrients. This method shows significant promise for sustainable food production.

A notable example is Quorn, which uses a fungus-derived microorganism to convert carbohydrates into protein via fermentation. This process yields mycoprotein, a nutritious protein alternative derived from fungal mycelium (28). Quorn made its market debut in 1985, as mycoprotein pioneer and is hence not a novel food.

The Flemish landscape includes:

- Bolder Foods, a company that specializes in protein-rich mycelium with fermented vegetable substrate via submerged biomass fermentation. They already launched their proprietary ingredient, MycoVeg™, as an animal-free alternative for soft, semi-hard and fresh cheeses.

- As part of the VEOS Group, spin-off Naplasol operates a production plant in The Netherlands where they specialize in mycoprotein as meat replacer. They offer semi-finished products B2B to drive a sustainable protein shift.

- Startup Calidris Bio leverages microorganisms to efficiently convert unique substrates into a high-quality protein source. Their microbial protein is rich in essential amino acids, vitamins, and prebiotics, making it an excellent ingredient for pet food, aquaculture, and human nutrition.

- Citribel has been a leading supplier of citric acid in Europe since its establishment in 1919. The company utilizes a unique surface fermentation process involving *Aspergillus niger*, which produces not only citric acid and citrates but also fungal mycelium. While this mycelium is now primarily used as animal feed, Citribel is exploring its potential as a versatile biotechnology platform.

Cultured meat and fish

Cultured meat and fish result from animal cell lines who are cultured in controlled bioreactors to produce meat and fish analogue products without the need for traditional livestock farming or fishing.

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This technology offers ethical, sustainable, and safe alternatives to conventional meat and fish (29). The controlled production systems exclude the risk of contamination by pathogens, toxins, or pollutants, resulting in safer food for consumers.

- In Flanders, a notable startup is **Fishway**. Founded in 2022, the company's innovative approach involves culturing fish muscle and fat tissue cells in a bioreactor. This process allows for the production of fish products that are rich in essential nutrients like highly unsaturated omega-3 fatty acids (EPA and DHA). They thus aim to provide high-quality fish ingredients rather than ready-to-eat fish fillets, avoiding direct competition with traditional fishing and aquaculture.

3. *Insects and microalgae*

Alternative protein sources such as insects and microalgae are gaining interest as well. These sources offer not only sustainable protein but also serve as valuable processing aids in the production of high-value compounds.

- In Flanders, **FlyBlast** is leading the way with insect innovation. The startup focuses on the Black Soldier Fly (*Hermetia illucens*), leveraging its unique bioconversion capabilities to transform organic waste into high-quality protein and lipids. FlyBlast aims to reduce the costs associated with cultivated meat production by developing a more efficient growth medium derived from these insects.

- **Axabio** in contrary produces natural astaxanthin using innovative microalgae cultivation technology. The company specializes in cultivating the microalgae *Haematococcus pluvialis*, known for its high astaxanthin content. By harnessing the potential of microalgae, Axabio aims to provide a sustainable and effective alternative to synthetic astaxanthin.

4. *Biocatalysis*

Enzymes, as natural catalysts, facilitate highly efficient chemical reactions under conditions where high selectivity and mild environments are required. Biocatalysis offers numerous applications as an alternative to chemical catalysis, reducing the need for high energy-input, harsh chemicals and extreme processing. The clean reactions it facilitates also simplify downstream processing, making it easier to adopt in chemical production compared to fermentation. Furthermore, advanced methods in enzyme engineering and computational enzyme design have expanded the scope of biocatalysis (30).

- Noteworthy companies with a presence in Flanders and active in this field include IFF (International Flavors & Fragrances), Cargill and **Ajinomoto Omnichem**.

- Specific startup exalples are Ryb Labs and Puxano. **Ryp Labs** is an innovative startup that focuses on using enzyme technology to extend the shelf life of fresh produce to reduce food waste. By developing enzyme-based coatings and treatments, Ryp Labs aims to address the global issue of food loss, ensuring that more food reaches consumers. In contrary, **Puxano** focuses on protein design, structure-based protein research, and production of tailored proteins through advanced biotechnological methods and AI.

5. *Advanced bioprocessing*

Advanced bioprocessing and manufacturing techniques are crucial for scaling up biotechnological innovations from the lab to industrial-scale production. These processes ensure the efficient, cost-effective, and sustainable production of bio-based products, including fuels, chemicals, and food ingredients.

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- Bio Base Europe Pilot Plant is a state-of-the-art facility that supports research, scaling up and first-series production of fermentation-derived and biomass products. Offering expertise and infrastructure from lab to 75,000 L scale for the scale-up and demonstration of new biotechnological processes, the organization plays a key role in advancing the commercialization of these products. Dozens of products have reached introduction into the market and more than 500 million EUR has been invested in new production facilities all across Europe.
- ILVO's Food Pilot is a research and development platform focused on food processing and bioprocessing. The Food Pilot supports the development of new food products and processes, providing the necessary infrastructure to test and scale up innovations in the food industry.
- Avecom also contributes to this ecosystem by specializing in sustainable solutions for environmental remediation, side stream valorization, and microbiology-driven solutions.

In addition, a notable initiative is the **Steelanol project** at ArcelorMittal in Ghent. The project is a pioneering example of how biotechnology can transform industrial waste into valuable products, specifically by converting steelmaking waste gases into bioethanol through gas fermentation. This process uses engineered microorganisms to convert carbon monoxide (CO) from industrial emissions into ethanol, which can then be used as biofuel or chemical feedstock, significantly reducing the plant's carbon footprint. Other examples for a circular, bio-based economy include Alco Bio Fuel, which processes grains (mostly corn) into bio-ethanol and other bio products, and startups More2Coffee and B3ET.

6. Green extraction

Green extraction involves the use of sustainable methods to isolate valuable compounds from agricultural biomass. These processes, performed at UHasselt (CMK) prioritize environmental friendliness by employing natural deep eutectic solvents (NADES), which are biodegradable and non-toxic alternatives to conventional solvents. This innovative green extraction enables the production of bioactive substances, such as biostimulants and biopesticides, which enhance plant health and contribute to sustainable horticulture.

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ANNEX 2: New Genomic Techniques

Background: relevance of the European NGT proposal

An appropriate regulatory framework for crop genome editing has long been necessary. To address this, the European Commission launched a proposal to modernize European legislation, distinguishing New Genomic Techniques (NGTs) from traditional genetically modified organisms (GMOs) based on the nature of the genetic alterations involved (4). On February 7 2024, the European Parliament voted in favour of this proposal, marking significant progress for green biotechnology in Europe. However, negotiations with EU member states await finalization, crucial for Europe's competitiveness. A well-balanced approach will ensure that innovation in plant biotechnology continues to thrive, benefiting academics, industry players (incl. SMEs), farmers and the overall agricultural landscape in Europe.

Current policy landscape

Plant Breeders' Rights and Patentability

Developers of new conventionally bred plants can obtain protection for their innovation through Plant Breeders' Rights (Plant Variety Protection, PVP). However, specific plant traits resulting from non-essentially biological methods - including advanced biotechnological techniques - may be patentable.

Using innovations that are covered by intellectual property rights (PVP or patents) for developing further innovation is supported by the current legal framework:

- For conventionally bred plants, the innovation lies in the total genetic combination. This can be protected by Plant Breeders' Rights. Using the protected innovation to develop new innovations by breeding is allowed. Using the identical, protected innovation by 3rd parties for commercialization is prohibited.

- For traits, the innovation lies in the specific sequence in combination with the tools used to achieve it. These traits can only be protected by patents. Using the protected innovation to develop new innovations by modifying the trait is allowed (research exemption). Also, the transfer of the protected trait to other germplasm to explore its function is allowed (breeders' exemption). Using the identical, protected innovation by 3rd parties for commercialization is prohibited.

NGTs in microorganisms

The current GMO framework for release into the environment, and thus bringing to market of products, was built with a focus on plants. This is not sufficiently suitable for microorganisms used in a live form as products, with the corresponding result that there are currently no such microorganisms in the risk assessment pipeline for future commercialization in the EU.

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ANNEX 3: Biocontrol products

Background: relevance of biocontrol products

Most of the currently authorized plant protection products rely on synthetic chemicals developed decades ago. Consequently, older chemical methods - despite improvements in their safety profiles - remain widely used. The over-reliance on chemical plant protection products has resulted in biodiversity loss, degraded soil health, and growing concerns on their residues in food. In addition, many pests have developed resistance to commonly used plant protection products, rendering these products increasingly ineffective (31). This makes the need to significantly reduce their use in European agriculture more urgent than ever. Although the EU's Farm to Fork Strategy set ambitious goals to address these issues, it no longer provides sufficient momentum for the necessary shift towards more future-proof alternatives. The Sustainable Use Regulation (SUR) was meant to support these efforts by aiming to halve chemical pesticide use by 2030, and providing a regulatory framework for responsible use of chemicals while promoting safer alternatives. However, the recent withdrawal of the SUR marks a major setback for the Farm to Fork Strategy.

Current policy landscape

No clear definition for biocontrol products

To achieve meaningful chemical pesticide reduction, farmers need access to a broader toolkit of alternatives. Integrated Pest Management (IPM) is key to this approach, allowing farmers to use biological, physical and other non-chemical methods in combination with selective chemical use for pest control. Promising alternatives are biocontrol products, which use natural organisms or substances to control pests in a targeted and more environmentally friendly manner. These products lower resistance risks and reduce harm to ecosystems and non-target species (32).

A clear definition of biocontrol products is essential for regulatory consistency across EU states. IBMA proposes a definition on their website categorizing biocontrol products in four main groups: microbials, semiochemicals, natural substances and invertebrate biocontrol agents (33). This definition may evolve with technical progress and scientific developments (10).

Burdensome, insufficiently adapted authorization procedures

Despite their potential, biocontrol products in Europe face significant regulatory hurdles. Their lengthy, costly, and complex registration process means that only products already in development or undergoing approval will contribute to short-term pesticide reduction goals. With the withdrawal of the SUR, it is even more crucial to streamline and speed up approval and authorization to make biocontrol products more accessible to farmers.

In addition, the current implementation of Regulation (EC) No 1107/2009 is not well-suited for evaluating non-chemical solutions. While including biocontrol products can provide temporary relief, there is a need to consider new legislation - a dedicated regulatory framework specifically designed for biocontrol products.

The current situation creates an environment of uncertainty that discourages new entrants, such as SMEs and startups, to invest and develop biocontrol products for the European market at full speed.

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ANNEX 4: Microbial biostimulants

Background: relevance of microbial biostimulants

Microbial biostimulants, which contain live beneficial microorganisms like bacteria, are not as such inputs of nutrients, but nevertheless stimulate plants' natural nutrition processes. Independently of the product's nutrient content the sole aim is of improving one or more of the following characteristics of the plant or the plant rhizosphere:

- nutrient use efficiency;
- tolerance to abiotic stress;
- quality traits;
- availability of confined nutrients in soil or rhizosphere.

Global demand for biostimulants is on the rise, with the European market projected to grow at a compound annual growth rate (CAGR) of 10.71% from 2024 to 2029, maintaining Europe's lead since the global market valued at USD 2.24 billion in 2018 (33).

Current policy landscape

Biostimulants have no direct action against pests, and therefore do not fall within the regulatory framework of pesticides. However, since July 16, 2022, they are formally recognized as a category in the EU Fertilizing Products Regulation (FPR, (EU) 2019/1009) setting unified standards for safety, quality, and efficacy across the EU's 27 member states. The FPR represents an important step forward by establishing regulations for biostimulants within a harmonized framework, supporting the integration of these products into sustainable agricultural practices across Europe. However, limitations within the FPR - specifically under Component Material Category (CMC) 7 - constrain the growth and innovation potential for microbial biostimulants.

Restricted positive list under CMC 7

The FPR's CMC 7 currently restricts market access to only four types of microorganisms (*Azotobacter* sp.*,* Mycorrhizal fungi*, Rhizobium* sp.*,* and *Azospirillum* sp.*).* This restricted positive list hinders market access for other effective microorganisms that are used in national markets or are under advanced research. This limitation presents several challenges:

- **Fragmented market access**: The restrictive nature of CMC 7 preserves national-level differences in microbial biostimulant regulation, creating regulatory fragmentation across the EU. Many microbial biostimulants approved at the national level in certain member states cannot be marketed EU-wide, limiting both competition and innovation.
- **Impacts on innovation and R&D**: Excluding microorganisms beyond the positive list can hinder research and innovation by creating a bottleneck for products that are otherwise safe and effective but lack EU-wide regulatory recognition.
- **Administrative and financial barriers**: Companies seeking to introduce new microbial biostimulants face additional administrative and financial burdens to comply with both EU and national regulations, impacting the growth potential of SMEs and new entrants in the market.

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ANNEX 5: Novel foods

Background: relevance of novel foods

Novel foods are increasingly relevant in addressing global challenges related to food security, health, and resource scarcity. Defined by the European Union as foods not widely consumed before May 1997, these may include innovative products like cultured meats, plant-based proteins, insect-based foods, and fermentation-derived products. However, despite their benefits, the current European regulatory landscape is not yet fully adapted to enable efficient commercialization of these new food sources on the European market.

Of course, ensuring the safety of novel foods remains a top priority, with rigorous evaluation required to maintain consumer trust. Yet, the complexity of the existing regulatory framework can pose significant barriers to innovation. While the European Union has established guidelines for novel foods, there remains a need for greater clarity and harmonization across member states to support the safe and timely introduction of novel food products on the European market.

Current policy landscape

Registration timelines

In the EU, EFSA oversees the authorization of novel foods, with stated registration timelines of nine months. In practice, however, this approval process often takes longer - even extending from several months to years. This delay is partly due to EFSA's **"stop-the-clock"** procedures, where the timeline is paused whenever EFSA requires additional information or clarifications from the applicant. This extended timeframe has led industry stakeholders to request greater transparency and increased interaction with EFSA throughout the application process.

Once EFSA issues a positive scientific opinion, the approval success rate is typically high *(Isabelle Laquiere, panel discussion, Open Food Conference, March 2024)*. Following this, the Plants, Animals, Food, and Feed (PAFF) Standing Committee finalizes the authorization. This committee is responsible for finalizing details, including the specific food categories in which the novel food can be used, the permitted levels of use, labeling requirements, proprietary data protections, and other safety specifications. These final steps help to ensure that the novel food is used safely and in a manner that aligns with regulatory standards across the EU.

Pre-approval tastings

Taste testing is a critical part of (novel) food development, directly impacting consumer acceptance and product success. However, current EU regulations prohibit taste testing of novel food products before EFSA approval. This restriction poses a significant risk: if an issue with taste or texture is discovered only after approval, years of investment in time and resources may be lost.

Allowing controlled early-stage tastings could enable companies to refine formulations to better match consumer preferences and to identify potential issues before committing to the lengthy regulatory process. This adjustment could also help streamline product innovation, allowing approved products to be market-ready in terms of flavor and consumer appeal. Ultimately, early-stage tasting could support both industry and regulatory goals, promoting food innovation while ensuring that novel foods meet consumer expectations and maximize the value of regulatory approvals.

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