DECHEMA
Gesellschaft für Chemische Technik
und Biotechnologie e.V.

PHYTOEXTRACTS

A sustainable resource for innovative products

Trends, Perspectives and Visions

https://dechema.de/Roadmap_Phytoextrakte_2025

Content

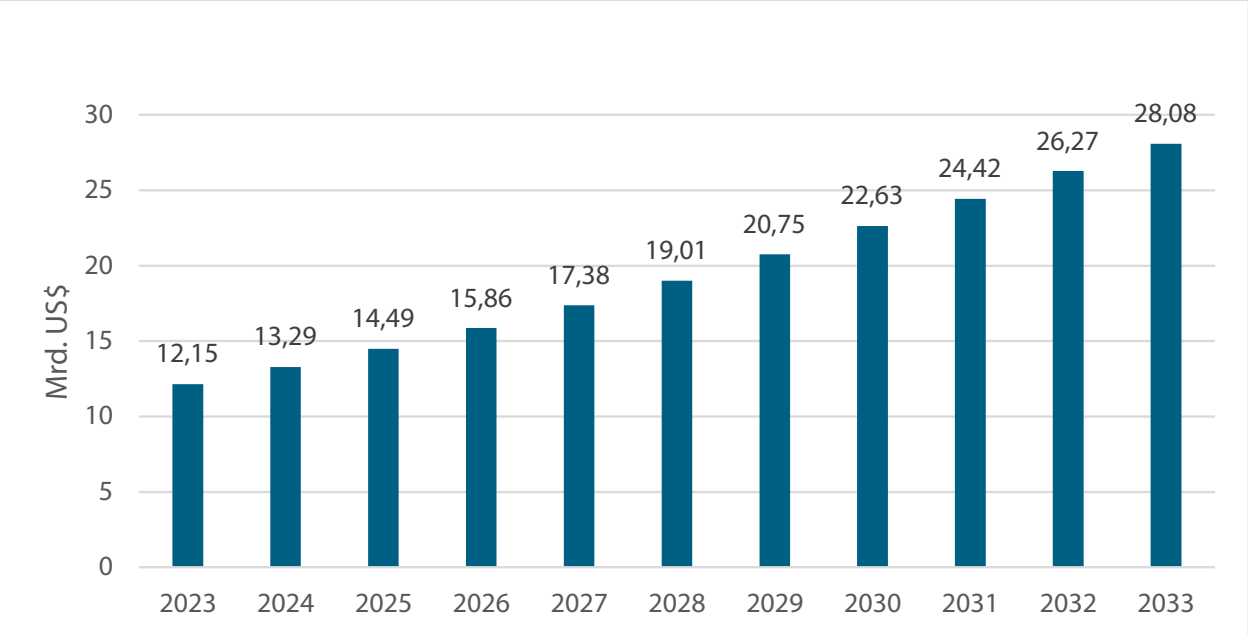
1. Introduction

The goal of climate neutrality and its implementation through the Green Deal, bioeconomy, biobased world, sustainability, resilience and circular economy can only be achieved in all areas through the involvement of plant-based raw materials.

As natural products made from renewable resources, plant-based extracts are perceived by end consumers as sustainable and “green”. They are key ingredients in cosmetics and perfumes, but are also used as odorants, flavorings and colorants and as hydrocolloids to adjust the viscosity of foods and beverages. They are also applied as food supplements and herbal medicines. Another area of application are naturally degradable pesticides or preservatives in the food sector (e.g. rosemary extract). In addition, they serve as auxiliaries in material production (tanning agents), as a scaffold substance for tissue engineering and tissue culture (alginates), as a source of nutrients for biotechnical production (malt extract) and as biochemical reagents for research and medical diagnostics (lectins). “Naturalness” is a key decision criterion for end consumers in all product areas. Significant contributions are made to the social benefits and needs of three of the five central areas of life, i.e. health, food and energy, with only rather small contributions to mobility and IT.

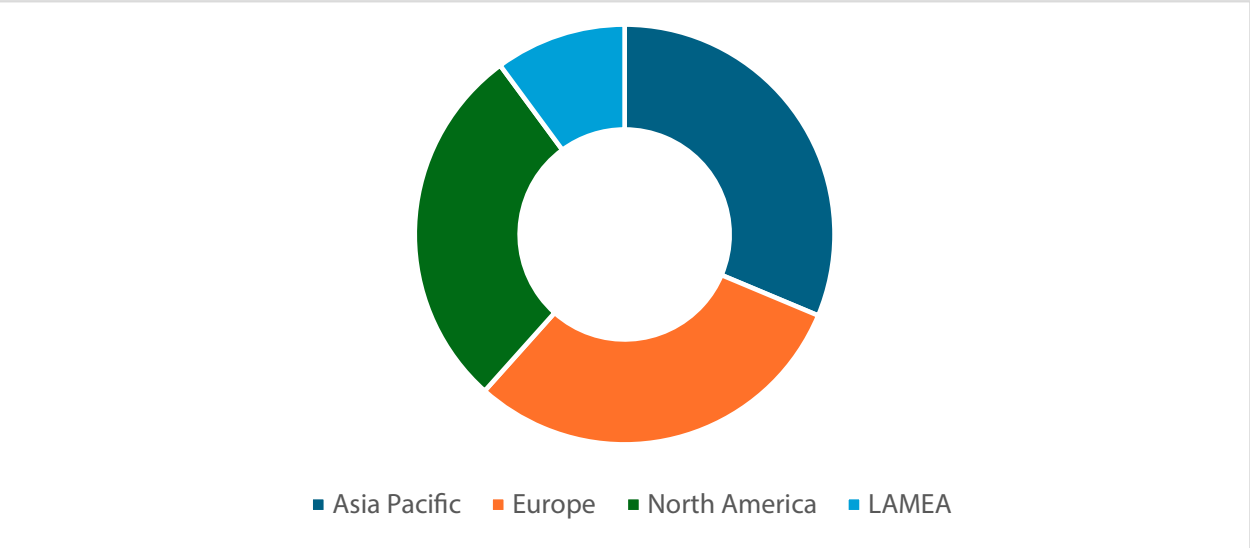
2. Market Overview

Studies predict a significant market growth, approximately doubling the market size within the next 8 years:



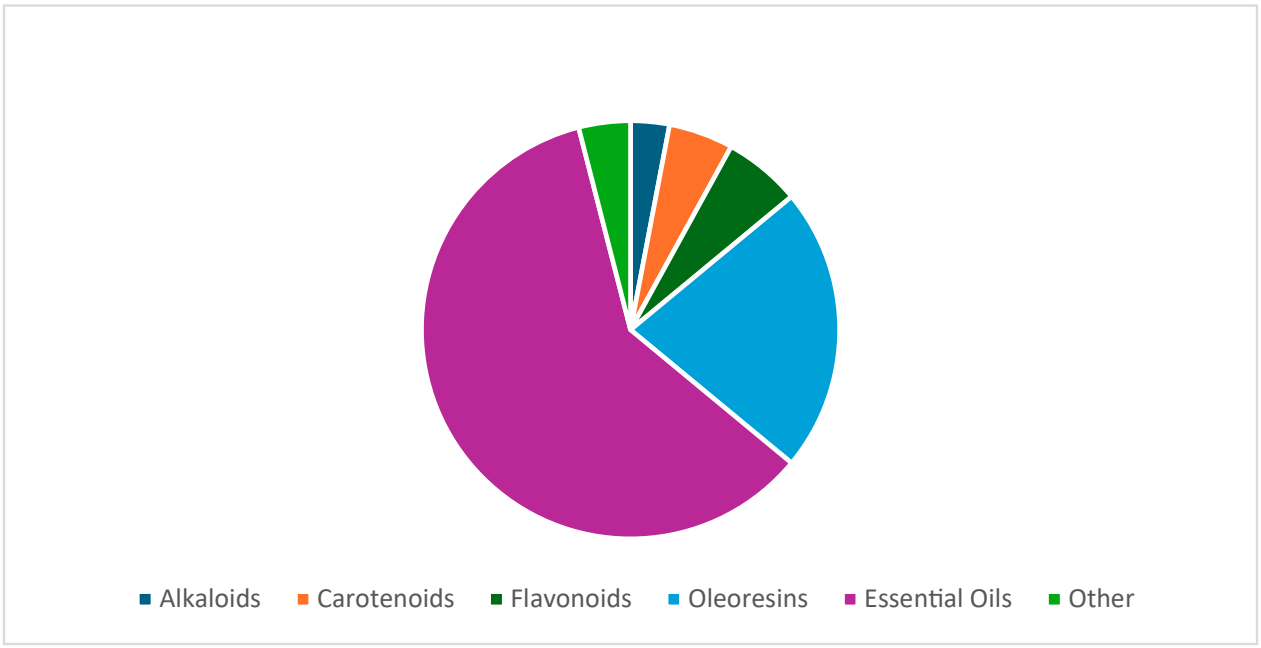
Graphic 1: Development of the global market for natural extracts 2023, source: Precedence Research (https://www.precedenceresearch.com/natural-extracts-market); accessed 20 February 2025

In terms of regions, there is a three-way split between Asia Pacific, Europe and North America with LAMEA, with Europe remaining significant.



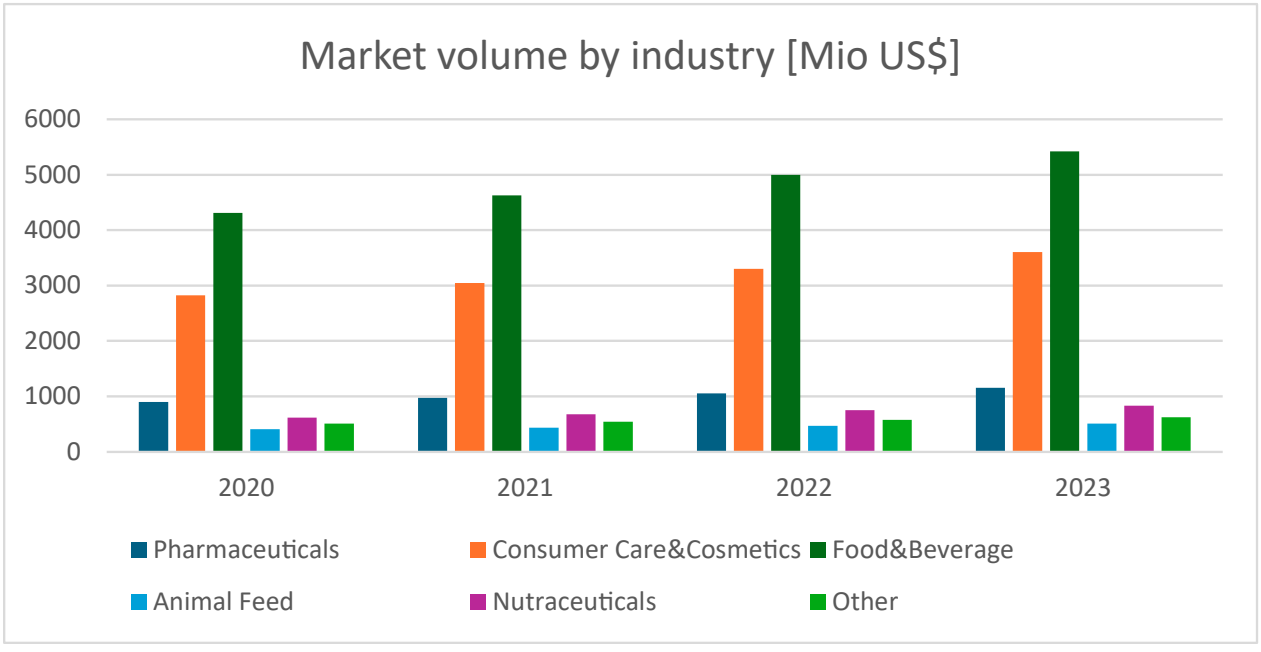
Graphic 2: Regional distribution of the global market for natural extracts 2023 [%], source: Precedence Research (https://www.precedenceresearch.com/natural-extracts-market); accessed 20 February 2025

Essential oils account for 60% of the market:



Graphic 3: Market share by substance class 2023 [%], source: Precedence Research (https://www.precedenceresearch.com/natural-extracts-market); accessed 20 February 2025

The market is distributed across several individual sectors with a clear dominance of Food & Beverage and Personal Care & Cosmetics:



Graphic 4: Market share by substance class 2023, source: Precedence Research (https://www.precedenceresearch.com/natural-extracts-market); accessed 20 February 2025

3. Industry Structure in Germany

The German natural product industry with a pharmaceutical focus is characterized by approx. 1,000 companies, 80% of which are SMEs, and thus almost entirely by small and medium-sized enterprises. This continues through approx. 100 extraction companies to approx. 1,000 companies that cultivate medicinal and aromatic plants with approx. 5,000 employees on approx. 10,000 ha, i.e. only a fraction of the approx. 17 million ha of agricultural land. Organic cultivation of medicinal and aromatic plants in Germany accounts for 1000 ha and approx. 70 farms, with approx. 30 full-time employees per 100 ha, i.e. approx. 300 in total[1].

Thus, the key numbers for the sector are estimated at

- a total sales volume of approx. 2.5 billion in the pharmaceutical sector, approx. 2 billion in cosmetics and fragrances, approx. 2 billion in food supplements, approx. 0.1 billion in spices & flavors, approx. 0.5 billion in agrochemicals and approx. 0.5 billion in cultivation,
- at least approx. 1,000 employees per approx. 100 pharmaceutical and food supplement companies, approx. 100 employees per approx. 100 extraction companies and approx. 1,000 employees at approx. 10 intermediaries and vendors as well as approx. 5,000 employees in the cultivation of the plants, i.e. a total of approx. 120,000 employees.

Taking suppliers into account, the industry can be estimated at a total market volume of around 10 billion € and around 200,000 employees – significantly more than, for example, the steel industry in Duisburg and Salzgitter whose ongoing transformation raises a lot of political and public concern.

4. Current Challenges for the Industry

This entire value chain, from breeding, cultivation, harvesting, extraction and production to formulation, is currently threatened by de-industrialization including loss of employment. The reasons are unclear regulations that are not harmonized in the EU, and that the market may not be able to cope with.

Relevant regulations
At EU level, there are several directives and laws that regulate the **cultivation, harvesting and processing of medicinal plants:**

1. Directive 2004/24/EC: this regulates the authorization of traditional herbal medicinal products and provides a simplified registration procedure for such products. It distinguishes between herbal medicinal products and food supplements, which leads to different requirements.

2. Good Agricultural and Collection Practices (GACP): These standards are crucial for the quality and safety of medicinal plants. They specify how plants must be grown, harvested and processed to ensure the efficacy and consistency of products.

3. Sustainability guidelines: International agreements such as the Rio Convention on Biological Diversity and CITES promote sustainable practices in the cultivation and harvesting of medicinal plants in order to protect biodiversity.

1 https://www.umweltbundesamt.de/umweltatlas/umwelt-landwirtschaft/einfuehrung/landwirtschaft-in-deutschland/wie-wird-die-landwirtschaftliche-flaeche-in

However, there are also national regulations that vary depending on the member state and can be applied through mutual recognition within the EU. However, this then creates considerable shifts in competition in favor of the national representatives with the least stringent requirements.

The EU Cosmetics Regulation (EC) No. 1223/2009 is the central regulation for **cosmetic products** in the European Union. It lays down requirements for safety, ingredients, labeling and bans on animal testing. Manufacturers must ensure that their products undergo a scientific safety assessment before they are sold. The regulation harmonizes the regulations within the EU so that products can be sold in all member states. However, there are differences between countries in terms of enforcement and sanctions for infringements. Some countries have additional requirements, e.g. specific regulations for nanomaterials or personalized cosmetics. In addition, national authorities may have different interpretations of EU regulations, leading to divergences. A key point is that the EU prohibits animal testing for cosmetic products, but conflicts may arise with other regulations, such as REACH in particular, which require animal testing for chemical safety assessments, which in turn prohibits approval as cosmetics.

The EU regulates **agrochemicals** mainly through Regulation (EC) No. 1107/2009, which governs the authorization of plant protection products and their active substances. This Regulation replaces the former Directive 91/414/EEC and lays down criteria for the authorization, use and residues of agrochemicals. The regulation is supplemented by specific regulations such as Regulation (EU) No. 540/2011, which lists approved active substances. The implementation of these EU regulations varies between Member States as national authorities are responsible for monitoring and enforcement. Differences may occur in the speed of approval procedures, the setting of maximum residue limits (MRLs) and the consideration of local environmental conditions. Some countries have stricter regulations, especially for controversial substances such as neonicotinoids, some of which are banned in the EU. In addition, international standards and trade agreements influence national regulation, which can lead to harmonization or divergence.

Depending on the final application of phytoextracts, other EU and national regulations such as the Feed Regulation (Regulation (EC) No. 1831/2003), the Biocidal Products Regulation (Regulation (EU) No. 528/2012 or ChemBiozidDV) or the Fertilizer Regulation (Regulation (EU) 2019/1009) may be relevant. These can also contain problematic requirements for complex and sometimes variable mixtures of substances, as is often the case with phytoextracts.

The consequences of these regulations include:

Cultivation

- Cost increases by 70%, since mechanical instead of chemical plant care is necessary in order to save on recognized and proven herbicides/fungicides/pesticides

Extraction and end product processing

- no equal treatment within the EU, but country-specific differences in the scope of testing for new product approvals
- no data-driven and risk analysis-based improvements to production technology permitted, therefore contrary to the efforts of the companies, no cost optimization for energy savings and GWP reduction possible

Classification and market access

- Even the reclassification and marketing of medical products as food supplements is only competitive in terms of process technology with a factor of 3-4 lower manufacturing costs2.
- This is only possible with innovative technologies (see below), which are not permitted in the pharmaceutical sector. Thus, processes that could allow for the competitive production of food supplements cannot be developed as long as a product is regulated under pharmaceutical law.
- there is hardly any knowledge-based advice from the authorities for food, cosmetics and pharmaceuticals due to the existing regulations

2 Expert estimate during the symposion.

5. Recommended Measures

To ensure the industry's competitiveness, it is therefore necessary

- to establish an equal treatment over all EU member states
- to promote technological innovations for implementation in order to minimize global warming potential in manufacturing and production
- Robots
  - in harvesting/cultivation applications
  - "Green" extraction processes with integration of breeding, cultivation, harvesting and formulation
  - Resource- and energy-efficient downstream processes using state-of-the-art chemical process engineering, including adsorption materials and membrane technology
  - Adaptation of the specific data requirements and methods required for registration. The currently valid methods (e.g. OECD) have largely been developed for pure substances and often cannot be easily transferred to complex mixtures of substances, as is often the case with plant extracts.
  - Risk analysis-based procedures similar to those already established for biologics which are comparably complex substance system mixtures, where in addition to the analytical methods, the process also defines the product quality (FDA/EMA QbD guideline). This creates the necessary flexibility for natural variances and enables product quality to be achieved efficiently.
  - Utilization of side streams from other industries in the sense of the circular economy
  - Expansion of the transfer of side streams using recycling innovations: Biogas plants with material CO_2 utilization; new resource-efficient production systems for high-quality food and materials (primary conversion by insects, fungi, microorganisms) to substitute fossil-based products as far as possible
  - If necessary, (co-)financing of toxicological and also clinical studies to finally clarify the questions raised by the authorities regarding efficiency, safety and harmlessness, for a:
- Data-driven dialog with the regulatory authorities to solve problems
- Ensuring IP protection via process and formulation patents, as in principle clinical study results are then accessible to all.

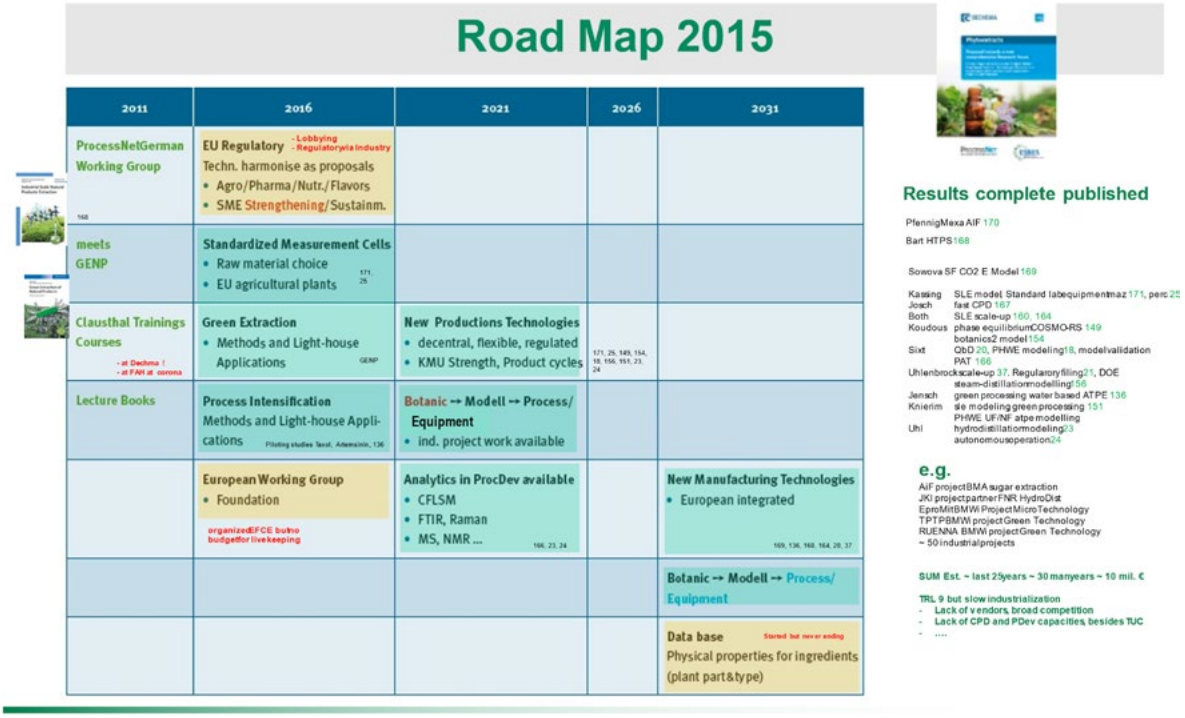
If the established indications of herbal medicinal products cannot be maintained or can no longer be maintained to the same extent due to more recent efficacy studies, then the transition to food supplements could take place with the definition of new claims in the status of a food. However, a drop in revenue by a factor of 3-4 is to be expected[3], so that optimized innovative manufacturing processes can and must be developed and used for specific substances in order to be economically attractive which is currently hindered as long as the product is subject for pharmaceutical regulation (see above). Funding for the new innovative production facilities should be provided in order to achieve industrialization.

3 Expert estimate during the symposion

6. Roadmap 2034: State of the Art

In order to provide researchers, technology developers, users but also political decision makers with a sound decision base, the DECHEMA/VDI Working Group on Phyroextracts has compiled the current technological state-of-the-art as well as expected and required developments in an updated roadmap.

The last roadmap was published in 2015. The tasks and goals of this roadmap have been executed and achieved over the recent years.



Thus, the DECHEMA/VDI Working Group on Phytoextracs organized a strategy symposium in Tutzing in November 2024 with experts from research and industry to discuss current challenges, and technological options for the further development of the field.

The results of these discussions are the basis for the new roadmap that in addition aims to respond dynamically to new global market and regulatory requirements.

From this, in the three subject areas
1. industrialization
2. side component valorization
3. technology innovation

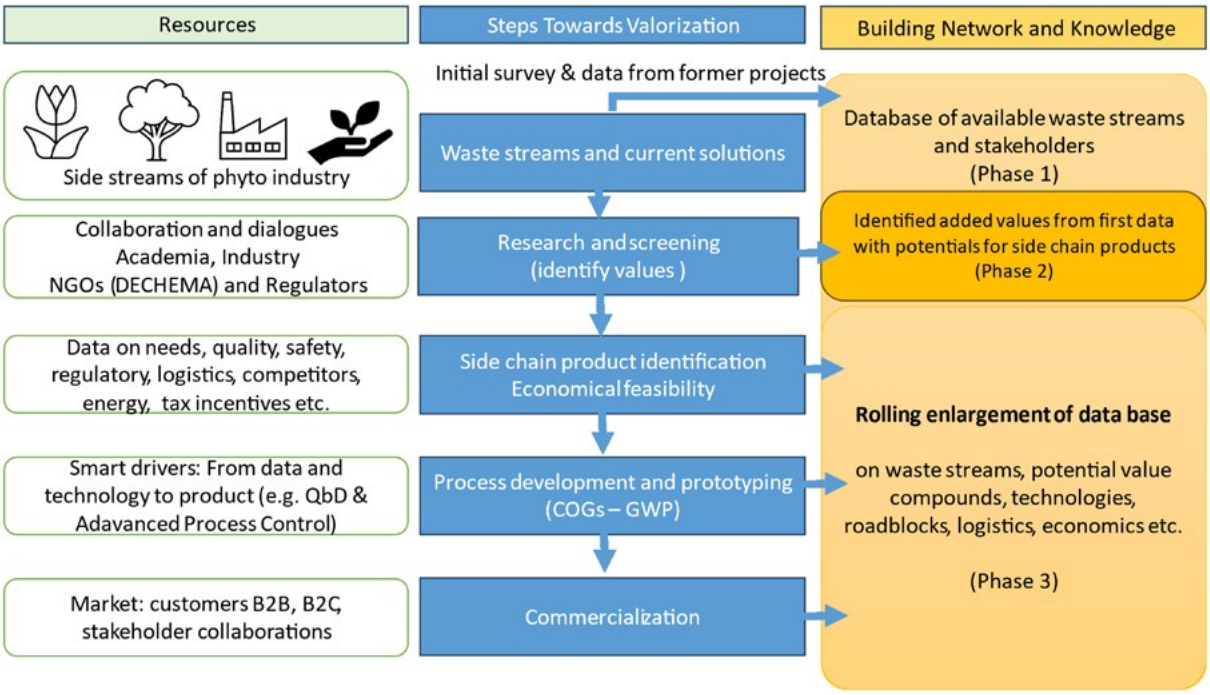
concrete project outlines for the Roadmap 2034 have been developed; these are summarized below:

7. Roadmap 2034: Developments

7.1 Industrialization

	2024	2026	2028	2030	2032	2034
Innovative Breeding	• Integrated farming systems • Development of new plant varieties • Awareness + acceptance for modern breeding methods • Favour high-value products in agriculture	Funding (grants, public funding and industrial investment)	• Long-term financial security • Developments			Increasing cultivation of medicinal and aromatic plants in Western Europe to mitigate climate change effects
Cultivation Harvesting	• Definition of needs and limitations based on end products • Plants as source for chemicals	• Robot weed cleaner required within ‹ 5 years to avoid 70% cost increase • Technical process from seed to harvest as alternative to handiwork, no big machines for chemical cultures	• Research on ingredients • New plants for new products • New methods for protein extraction and purification	• Substitute fossil resources with plants • Competitive price ratio for sustainable plant raw material		Subsidising with defined “fading out” of funding to translate innovation to industry
Interdisziplinary Networking Knowledge Sharing Platform	• Trainings Courses organized by DECHEMA • Provide funding for R&D activities at universities to increase process and equipment efficiency	• Strengthen communication along value chain -› create feedback and knowledge-sharing platforms (online)	• More cross section exchange • Early-stage feasibility and competitiveness evaluations of R&D topics	• Exchange on best-case examples and technologies, European Process Intensification	• Joint activities in scaling up development including chemical engineering and bioprocessing	More cross section exchange
Piloting & Scale-up Technology	• Adsorption, Desorption • Cavitation technologies (extraction, emulsification, dispersion, sonocrystallization) • Solvent-free methods	• Cost efficiency, • Business cases • Cross section solutions eg harvesting & processing	• Toolbox of downstream technologies including membrane technology	• Legislation framework • Approval to schedule • Commercial support -› subsidies		Innovative production technology investments co-funded
Regulatory	• Common EU regulation based on data-driven risk assessment	• Simplification of regulatory affairs • Revise legislation to favour taking responsibility and risks	• Regulatory solved in ‹ 3 years to avoid risk of EU deindustrialization	• Common food regulation in EU • Better IP protection for step-innovations • Higher burden of proof for authorities		• Regulatory quality definition • Risk based approach, data driven
Production Manufacturing technology	• Risk mitigation • Raw material • Production process • Authority approval • Market	• Process Integration • Extraction and Formulation • More robust technology / IT			• Production Plants • scale-up • Standards • Contractor/ • communication • Schedule • System integration	Automation from critical process attributes to breeding via harvesting – extraction- downstream-formulation incl data integration

7.2 Side Component Valorization



	2024	2026	2028	2030	2032	2034
Database	Building Network: Coordination with DECHEMA Groups	Initial Survey of Industrial Landscape				Ongoing Database Development
Side Chain Product: Value Identification			• Target Identification (Screening) • Quality Analytics of Side Stream	• Economical Feasability • Studies and Market Analysis		
Process Development and Prototyping					Available and Innovative Technologies	Scale up or Scale down Proof of Concept (GoGs & GWP)
Commercialization					Ease of Use and Logistics studies in interdisciplinary project	Proof of Concept

As a strategy for identifying lucrative side streams, several experimental studies at TRL 3 to 5 will be carried out from 2026 to 2028, in which the utilization potential of biologically similar and different side streams will be compared for a defined target substance (e.g. food proteins; flavoring agents; hydrocolloids). In a second phase, from 2028 to 2030, the utilization potential of the respective side stream will be evaluated, including other target substances. The studies will determine the application-related quality of the target substances, the production costs and the environmental impact. Various options for large-scale implementation will be examined up to 2032. The concepts deemed economically viable will then be scaled up.

7.3 Technology Innovation

Topic	2024	2026	2028	2030	2032	2034
Needs/ necessary steps				Digitalization achieved (no more paper)		
Automation		Replacement of old systems as support is shut down		Digital twins are commonly in place		Use of fully automated systems and processes is widely spread
Market demands				Climate Goal 2030	Joint activities in scaling up development including chemical engineering and bioprocessing	Significant contribution to Green Deal and Climate Change Acts
Regulatory needs	Call to assemble – regulatory/ industry/ academia think tank for green sustainable climate neutral future	Organizational structure finalized – first meeting	Joint outline-paper on common goals and necessary steps			Better approval situation due to adapted regulations for phytoextracts
Industrial acceptance/ application						Significant share of processes use innovative technologies to achieve green sustainable future
Research/ dissemination needs		Transfer of knowledge about new innovative technologies				

The execution and implementation of the Roadmap 2034 relies strongly on ongoing discussion within the expert community and beyond. The establishment of a continuous "Think Tank" bringing together academic and industrial experts with representatives of regulatory bodies will be key to developing a joint vision of an adequate regulatory framework. This is a prerequisite for industrial uptake of new processes and technology and ultimately fot the required contribution to achieving Europe's climate goals within the next decade.

The DECHEMA/VDI Working Group on Phytoextracts will accompany and enable this ongoing process. It has asked **all participants of the Tutzing Symposion to continue working together to implement this roadmap and to recruit other groups to participate.**

8. Imprint

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This publication has been written by experts of the DECHEMA/VDI-Working Group Phytoextracts with contributions by participants of the Tutzing Symposion 2024.

The Working Group Phytoextracts focusses on the extraction of valuable substances from plants. In addition to this source, these substances may also be obtained by fermentation processes in plant cells or microorganism. This is not covered by this roadmap.

Many thanks to all participants of the Tutzing Symposion for their valuable contribution!

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