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MEASURING WHAT MATTERS

Aligning Consumer Needs and
Benefits with Bioactives.

How to Coordinate Your Functional
Mushroom Products with Your
Customers' Expectations.


KÄÄPÄ Biotech
Nature is our laboratory.

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TABLE OF CONTENTS

02	Introduction: Industry Standards Lacking in the Functional Mushroom Industry
05	Why Beta Glucans are Insufficient for Quality Assessment
07	Specific Bioactive Compounds are Responsible for Health Benefits
08	Why Bioactives at the Right Dose Matters. The Science Behind it
15	New Quality Markers Necessary to Ensure Mushroom Efficacy
16	KÄÄPÄ Biotech’s Industry Leadership: Delivering on Bioactive Content and Certificate of Analysis
18	References



KÄÄPÄ Biotech is a biotechnology company committed to healthier humans and ecosystems. **Nordic Mushrooms**, the wholesale division of KÄÄPÄ Biotech, sells premium mushroom extract ingredients to companies across the world.

Visit kaapabiotech.com and nordicmushrooms.com to learn more.

1. INTRODUCTION

Industry Standards Lacking in the Functional Mushroom Industry

Current Market Landscape

Functional mushrooms, also known as medicinal mushrooms, are experiencing rapid growth, driven by a combination of consumer interest from social media, promising research, and a long historical use. Consumers increasingly seek out mushroom-based nutraceuticals for a wide range of health benefits like cognition, energy and performance, mood, relaxation, and longevity. This surge in popularity and the associated move of mushrooms into mainstream health and nutrition markets, has attracted many suppliers offering mushroom ingredients of varying quality.

With no clear industry standards or definitions, it's crucial for formulators and brand owners to understand the key criteria for selecting safe, high-quality mushroom extracts, meeting consumer needs. Most importantly, there is a requirement to have the right amount of bioactive compounds to ensure efficacy in delivering proven health benefits in the final product formulation.



The global functional mushroom market size was valued at USD 31.71 billion in 2023 and is expected to grow at a CAGR of 11.2% from 2024 to 2030. North America is the largest market today, accounting for approx. 45 % share of the total revenue. Functional mushrooms are used across Functional Food & Beverages as well as in Dietary supplements globally in various convenient delivery formats such as capsules, powders, tinctures, and infused products like coffee and teas.

Sources: SPINS, US, 2024 and Grand view Research
<https://www.grandviewresearch.com/industry-analysis/functional-mushroom-market-report>

Gap in Quality Standards

Industry standards have not kept pace with demand, leaving a critical gap in the consistency and efficacy of mushroom-based products. Today, most quality assessments in the functional mushroom industry hinge on basic parameters like beta-glucan content. However, beta-glucans alone are insufficient markers for the health benefits associated with different mushroom species.

Fruiting bodies, the part visible above ground, contain most of the bioactive compounds responsible for health benefits, whereas the mycelium, the underground hyphae and early growth stage of the mushroom, contain none or very low levels of the bioactive compounds. In regulatory terms, the mycelium is not always recognized under the definition of a mushroom to the point where the EU* classifies it as novel food and the U.S. FDA** has labelling requirements if the product doesn't contain mushroom fruiting bodies.

***European Food Safety Authority (EFSA):** Myceliated grain products are not approved as food products in the EU.

****U.S. Food and Drug Administration (FDA):** "Any food in which mushroom mycelium is used should be labeled to state that fact. Labeling should not suggest or imply that the food contains mushrooms."

Nevertheless, fermented mycelial grain, also known as FMG, is increasingly being passed on as functional mushroom ingredients, especially in the US market - even if this product has no comparison with the fruiting bodies.

A current lack of broader industry quality standards and reliable methods of analysis, allows sub-standard ingredients/extracts to be present in the market today. Without a shift to bioactive-based analytical standards, the potential of functional mushrooms cannot be fully realized. The industry needs reliable mushroom ingredients to ensure consistent and efficacious end products that consumers can trust, to secure long term success in the market.



2.WHY BETA-GLUCANS ARE INSUFFICIENT FOR QUALITY ASSESSMENT

Functional mushrooms, like Lion's Mane (*Hericium erinaceus*), Chaga (*Inonotus obliquus*), Cordyceps (*Cordyceps sinensis*), and Reishi (*Ganoderma lucidum*), have been extensively studied for their therapeutic properties.

However, current quality assessments in the industry disproportionately rely on beta-glucan content, a common polysaccharide found across many fungi and plants known for its immune-modulating effects. While beta-glucans provide immune health benefits, they lack the specificity required to capture the distinct effects of each mushroom species.

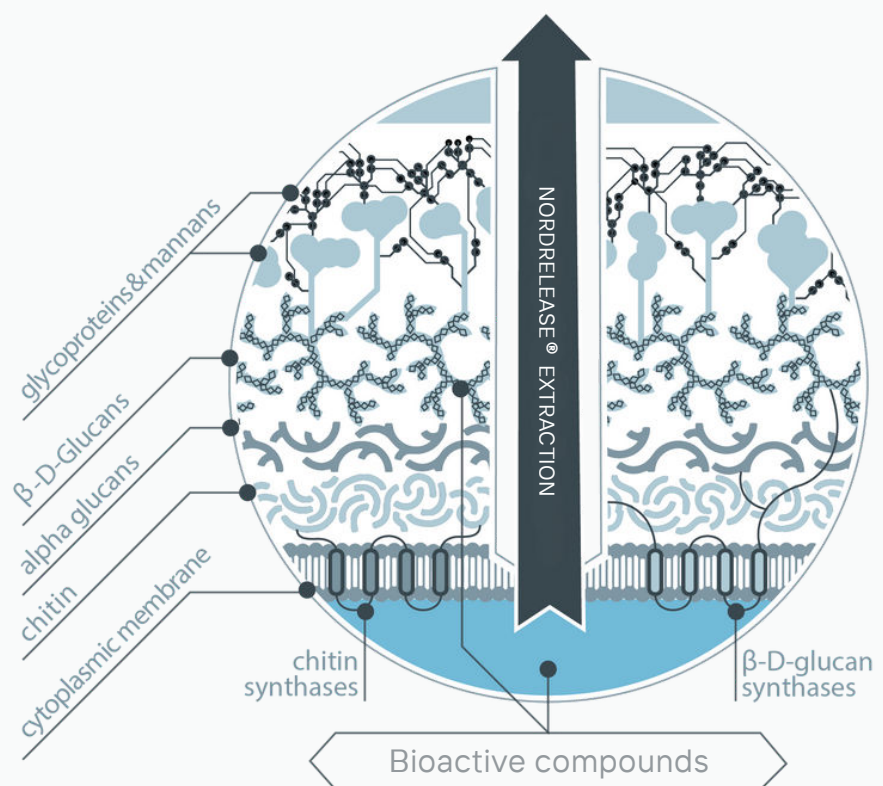
The problem with beta-glucan-only assessments is particularly concerning in functional mushrooms, where each species harbors unique bioactive compounds responsible for its specific health benefits. For instance, hericenones and hericenens in Lion's Mane are known for their neurotrophic effects, supporting cognitive health by promoting nerve growth factor (NGF) synthesis, a mechanism that beta-glucans do not address.



Moreover, fermented mycelial grain (FMG) contains a high level of glucans (indicated by polysaccharides tests) partly due to the growth substrate, but none or close to none, of the bioactive compounds responsible for the mushrooms' unique health benefits.

Moving beyond beta-glucans is essential to accurately measure and guarantee the therapeutic quality of mushroom extracts, with specific bioactive compounds as more reliable indicators of health outcomes.

NordRelease® Extraction Process



NordRelease® extraction technology offers a safer and more effective method to obtain the bioactive compounds inside the mushroom cell.

3. SPECIFIC BIOACTIVE COMPOUNDS ARE RESPONSIBLE FOR HEALTH BENEFITS

Functional mushrooms contain a broad range of naturally occurring bioactive compounds that drive their unique health benefits.

THE MOST IMPORTANT BIOACTIVES PER MUSHROOM SPECIES

LION'S MANE
(*HERICIUM ERINACEUS*)

Contains **hericenones**, and **hericenones**, which are shown to support neural health and cognitive function by promoting neurogenesis.



CHAGA
(*INONOTUS OBLIQUUS*)

Contains **inotodiol**, and **betulinic acid**. Chaga exhibits strong antioxidant properties that can modulate immune function and supports longevity.



CORDYCEPS
(*CORDYCEPS MILITARIS*)
(*CORDYCEPS SINENSIS*)

Known for **cordycepin** and **adenosine**, compounds that enhance ATP production, making Cordyceps popular for energy and endurance sports.



REISHI
(*GANODERMA LUCIDUM*)

Contains **triterpenoids** associated with immune modulation, stress relief, and sleep support.



By focusing on these bioactive compounds, product formulators and manufacturers can more precisely target the health benefits associated with each mushroom. A high level of these bioactives are only found in premium mushroom extracts made from fruiting bodies.

4. WHY BIOACTIVES AT THE RIGHT DOSE MATTERS. THE SCIENCE BEHIND IT.

An increasing body of science supports the bioactive compounds found in functional mushrooms, their mechanisms of action, and their demonstrated health benefits after acute – short term, or chronic – longer term intake. Nevertheless, some uncertainty remains of the dose required to obtain the desired health benefits, and specifically how to best estimate the effective daily dose based on the level of bioactives found in the specific mushroom extract.

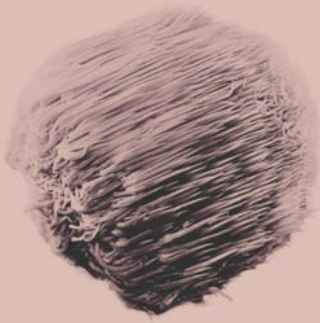
This scientific review by KÄÄPÄ Biotech's science team highlights the key bioactive compounds in various functional mushroom species and examines their role in contributing to functional health benefits, offering insights to guide product formulation and quality assessment.

Scientific Review Methodology:

This scientific review draws upon high-quality, peer-reviewed in-vivo studies to assess the potential efficacy of mushroom-derived bioactive compounds. Given the current limited availability of clinical trials, in-vivo research serves as a valuable foundation for understanding the physiological effects of these compounds and their relevance to human health.

To evaluate the presence and relevance of key bioactive compounds, we conducted an internal analysis of the estimated bioactives content in the mushroom extracts or samples used in the published studies. This approach allowed us to contextualize the findings within a standardized framework for assessing extract quality.

As a benchmark for this assessment, the average composition of bioactive compounds found in **KÄÄPÄ Biotech's NordRelease®** range was used as a reference. This comparative framework supports industry stakeholders in evaluating the functional quality of mushroom ingredients, with a focus on the bioactives that are most closely associated with the health benefits.



Lion's Mane (*Hericium erinaceus*)

Key Bioactives: Hericenones and Hericenenes.

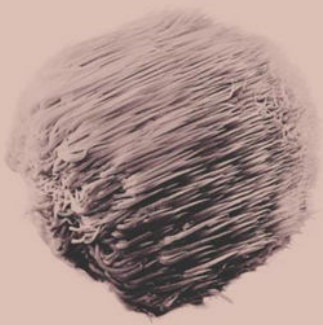
Scientific Evidence: Lion's Mane is renowned for its neuroprotective and cognitive-enhancing effects. This is largely due to the presence of hericenones, and hericenenes, which stimulate the production of nerve growth factor (NGF) and nerve regeneration.

A 2023 study with **NordRelease® Lions Mane** extract powder (La Monica et al. 2023) demonstrated acute effects on cognitive improvements and mood with **NordRelease® Lion's Mane** extract powder:

- **Improved Concentration, Working Memory, and Impulse Control**, with significant enhancements noted at 120 minutes compared to baseline and 60 minutes.
- **Mood and Clarity:** users reported significant improvements in measures of mood and mental clarity.

Level of Bioactives/Dose indication: According to the above acute clinical study, **NordRelease® Lion's Mane** extract powder delivered significant cognitive and mood support benefits. A review of the current scientific literature further suggests a lower dose is likely sufficient to obtain similar benefits if the key bioactive compounds are present at an efficacious concentration.





Lion's Mane (*Hericium erinaceus*)

Standardization of the levels of the Bioactive Compounds responsible for the functional benefits

Two key in-vivo studies which showed clear cognitive benefits measured the per dose content of hericenones, one of the key bioactives found in Lion's Mane fruiting bodies which are responsible for cognitive effects (Ratto et al. 2019, Roda et al. 2021). These studies reported that hericenone content in the sample material used was 0.05%.

Using existing studies as a reference for effective dosing in Lion's Mane, we analyzed the concentration of key bioactive compounds – such as hericenones and hericenens – present in **NordRelease® Lion's Mane extract**. This comparison highlights the importance of standardized extraction methods to ensure consistent and effective levels of these bioactive compounds in finished products.





Chaga (*Inonotus obliquus*)

Key Bioactives: Betulinic Acid, Inotodiol.

Scientific Evidence: Known for its potent antioxidant properties, Chaga contains compounds such as triterpenoids and polysaccharides. Betulinic acid and inotodiol have been shown to help protect against oxidative stress, support immune function, and regulate gut microbiota. Chaga also has the ability to inhibit oxidative DNA and RNA damage, which is crucial for maintaining cellular health.

These benefits were investigated by Giridharan et al. (2011) who showed significant antioxidant capacity of Chaga as well as potential cognitive dysfunction mitigation. In this in-vivo study, the authors utilized a dosage of Chaga equivalent to 243 mg in humans.

Standardization of the levels of the Bioactive Compounds responsible for the functional benefits

According to the scientific review, betulinic acid and inotodiol are identified as the primary bioactive compounds contributing to Chaga's distinctive health effects. The standardized levels of these compounds in **NordRelease® Chaga extract** represent a new industry benchmark for product developers, highlighting their importance as indicators of both quality and functional efficacy. As such, the focus on quantifying and standardizing these specific bioactives should be prioritized in formulation and product development strategies.



Cordyceps (*Cordyceps militaris/sinensis*)

Key Bioactives: Cordycepin, Adenosine.

Scientific Evidence: Cordyceps has been shown in several studies to boost athletic performance, improving aerobic capacity (VO_2 max) and oxygen utilization. Adenosine is the core molecule of ATP while cordycepin supports cellular energy metabolism associated with ATP production. Together these key bioactives contribute to improved energy, endurance, and reduced fatigue.

A key in-vivo study by Choi et al. (2020) demonstrated a clear link between the bioactive compound cordycepin and biomarkers associated with ATP generation, highlighting its role in energy production and metabolic support. The authors reported using fruiting body extracts with a cordycepin concentration of 2.33 mg/g and a dosage equivalent to 243 mg in humans. This study provides a valuable reference point for understanding how specific concentrations of bioactive compounds relate to measurable physiological effects.

Standardization of the levels of the Bioactive Compounds responsible for the functional benefits

According to the scientific review, cordycepin and adenosine are the principal bioactive compounds responsible for the health-promoting effects of Cordyceps, particularly in areas related to energy and metabolism. The standardized levels of these compounds, as found in **NordRelease® Cordyceps extract**, should be a primary focus for product developers. Measuring and standardizing these bioactive constituents is essential for ensuring consistency, efficacy, and scientific credibility in product formulation.



Reishi (*Ganoderma lucidum*)

Key Bioactives: Triterpenoids, Ganoderic Acid, Lucidenic Acid.

Scientific Evidence: Studies show Reishi's triterpenoids and polysaccharides help reduce stress and support immune function. Renowned for its calming and adaptogenic properties, Reishi triterpenes, specifically lucidenic acids, are associated with promoting relaxation and sleep.

Key studies by Chu et al. (2007) and Cui et al. (2012) provided detailed insights into the mechanisms underlying Reishi's sedative effects and its potential to improve sleep quality. In both studies, statistically significant effects were observed at a human-equivalent dosage of approximately 777 mg. These findings help establish a valuable reference point for understanding the relationship between Reishi extract composition and its physiological effects.

Standardization of the levels of the Bioactive Compounds responsible for the functional benefits

According to the scientific review, triterpenoid compounds – particularly lucidenic acid – are identified as the key bioactives responsible for Reishi's calming and sleep-supporting properties. The standardized levels of these compounds found in **NordRelease® Reishi extract** represent a reliable benchmark for product developers. Prioritizing the measurement and standardization of triterpenoid content is essential for ensuring the consistency, efficacy, and credibility of Reishi-based formulations.

In summary, the evidence reviewed across the various mushroom species indicates that distinct bioactive compounds, rather than broad compositional markers, are primarily responsible for the observed health benefits. The identification, quantification, and standardization of these specific compounds are critical for ensuring both the functional efficacy and compositional consistency of functional mushroom products. Accordingly, these bioactives should be regarded as essential quality markers, providing a scientifically grounded basis for formulation strategies in the development of next-generation nutraceuticals and functional food ingredients.



5. NEW QUALITY MARKERS NECESSARY TO ENSURE MUSHROOM EFFICACY

Given the unique bioactive profiles of different functional mushrooms, the industry must adopt new quality markers beyond beta-glucans to ensure therapeutic efficacy. Brand owners and formulators should adopt bioactives as key criteria when sourcing ingredients and choose quality suppliers, able to document the quality and efficacy of the ingredients on batch level for the key bioactive compounds.

Key Quality Requirements

- **Bioactive-Specific Testing:** Establish quality markers focused on specific bioactives relevant to each mushroom species.
- **Consistency Checks:** Ensure product potency with consistent bioactive content across batches.
- **Standardized CoAs:** Include bioactive content on Certificates of Analysis (CoAs) and provide scientific evidence supporting health benefits



6. KÄÄPÄ BIOTECH'S INDUSTRY LEADERSHIP

Delivering on Bioactive Content and Certificate of Analysis

Driving Accountability and Transparency

KÄÄPÄ Biotech is a vertically integrated functional mushroom ingredient supplier who takes leadership in transparency and efficacy. **KÄÄPÄ Biotech's Nordic Mushrooms** division is unique in offering detailed product information on bioactive content and linking it to science and health outcomes – setting the new global benchmark for quality in functional mushroom products.

KÄÄPÄ Biotech operates with full control and transparency in raw materials and processing steps and has the ability to document consistent quality with a guaranteed high level of bioactives per gram in any given batch of product.

Reliable analytical methods and quality control measures guarantee these attributes - and clinical studies are being carried out to support the health benefits of the extracts. This further adds to credibility and marketability.



Certificate of Analysis (CoA)



Transparency: A comprehensive CoA ensures that product formulators and consumers are informed about bioactive content, helping establish trust and repeat purchase.

Efficacy and Accountability: CoAs specifying bioactive compounds, dosing, and scientific validation foster accountability and align product quality with industry-best practices.

In conclusion, only by using reputable mushroom ingredient suppliers can brand owners ensure a consistent level of the desirable bioactives, guarantee the efficacy of their supplement brand, and meet the quality requirements of the retailers and online sellers today. And most importantly, provide consumers with the health benefit they expect – building consumer trust and confidence in the final products.

Nutraceutical companies are encouraged to adopt bioactive-focused quality standards, ensuring that functional mushroom extracts provide the promised health benefits and support a robust, science-backed industry.

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