Akkermansia myxophilus (AKK) Global Progress Report

2026

Data Cutoff:
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01. Basic introduction to AKK strains

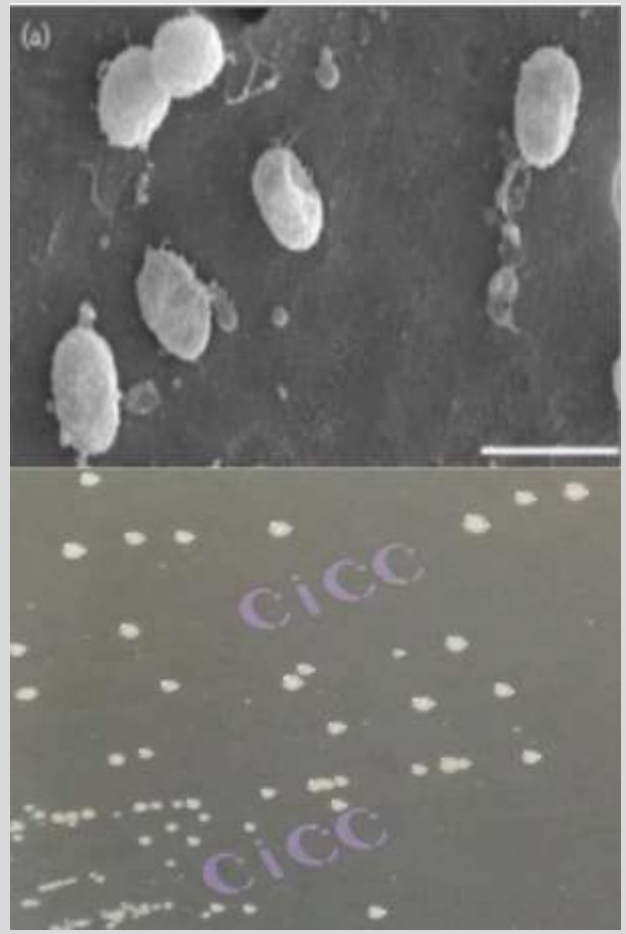
AKK

Akkermansia muciniphila (AKK) is the only known species of Verrucous microbe in the mammalian gut. It was first isolated and named by Derrien et al. in 2004 from fecal samples of healthy adults. The specific epithet "muciniphila" reveals its unique survival strategy—using mucin from the intestinal mucus layer as its sole carbon and nitrogen source, with its main metabolic products being short-chain fatty acids such as acetic acid and propionic acid.

The phylum Verrucomicrobia, genus Akkermansia, currently contains three species:
Akkermansia muciniphila
Akkermansia glycaniphila
Akkermansia biwaensis

AKK bacteria account for approximately 1%–3% of the gut microbiota in healthy adults. They reside between the intestinal mucus layer and intestinal epithelial cells, maintaining the dynamic balance of the mucus layer by degrading mucins and stimulating goblet cells to generate new mucins. This dual role helps maintain the integrity of the intestinal barrier.

The optimal growth temperature and pH for AKK bacteria are 37 ℃ and 6.5, respectively, but they can also grow at 20 ℃ to 40 ℃ and pH 5.5 to 8.0.



Traditional probiotics vs. "Next-Generation Probiotics"

Traditional probiotics mostly come from fermented foods with a long history, mainly Lactobacillus and Bifidobacterium.

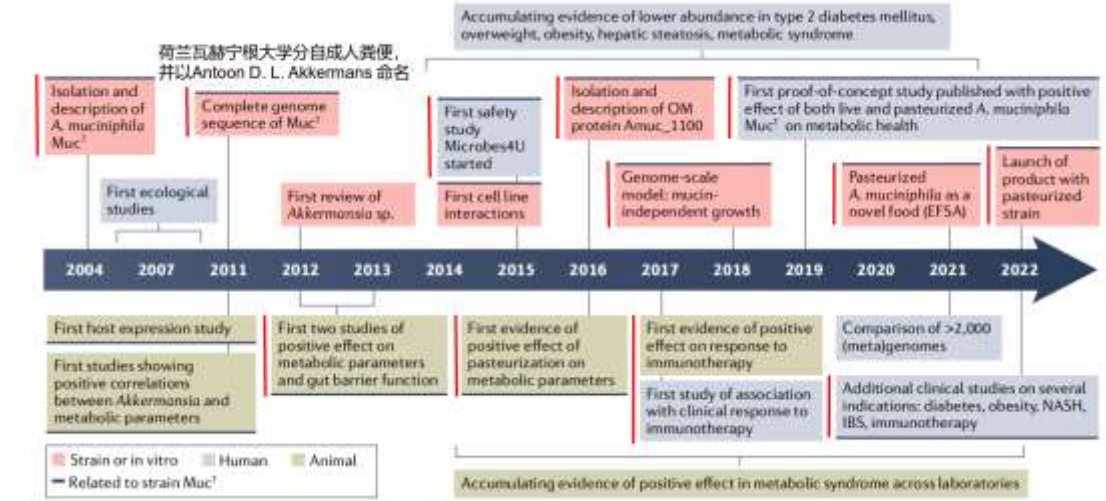
Next-generation probiotics (NGPs) are microorganisms that have been identified and isolated in recent years due to the rapid development of sequencing technology. They have never been used in the food industry before and mainly come from the bodies of humans and animals.

AKK bacteria have been clearly defined as the leading species of "next-generation probiotics" (NGPs).

Compared to traditional probiotics, NGPs represent a qualitative leap.

Dimension	Traditional probiotics	AKK（NGPs）
strain source	Fermented foods, environment	Human gut symbiotic flora
Mechanism of action	Generalization (Gut Health Regulation)	Precision (targeting specific metabolic/immune pathways)
Training difficulty	Relatively easy (aerobic/facultative anaerobic)	Extremely difficult (strictly anaerobic)
Business Objectives	Maintaining daily health	Clinical-level precision intervention

02. AKK bacteria research and development



2004: Derrien et al. first isolated and identified AKK bacteria at Wageningen University.

2011: Whole genome sequencing completed; no generational differences existed between Chinese and foreign companies in the initial stages.

In June 2025, Danone officially acquired The Akkermansia Company (TAC), gaining access to its patented strain Akkermansia muciniphila MucT®. This acquisition marked a milestone for AKK bacteria, moving them from the laboratory to the global food industry. TAC's pasteurized inactivated AKK products have already entered the European, North American, and Asian markets.

Industry Impact:

***This signifies that AKK bacteria have officially entered the supply chain of a global food industry giant;**

***It sends a clear market signal: In the "SmithRactopeptide Era," AKK bacteria, as a natural and safe alternative/auxiliary solution for weight management, possesses enormous commercial value;**

*** The entry of a major company will drive improvements in AKK bacteria in terms of standardization, safety, and consumer awareness.**

2013: The Necker research team in Paris published the first study on the association between AKK bacteria and obesity.

2014-2015: Global research entered a period of acceleration, with China making significant contributions in related research.

2016: The Akkermansia Company was established in Belgium, based on joint research findings from UC Louvain and WUR.

2019: Depommier's team published a landmark human clinical trial (32 participants, 12 weeks) demonstrating that pasteurized inactivated AKK improves metabolism.

2021: EFSA became the world's first organization to approve pasteurized inactivated AKK bacteria as a novel food.

2025: Danone acquires The Akkermansia Company; China's first application for a new food ingredient containing AKK bacteria is accepted.

03. AKK bacteria efficacy and application

Core health benefits

The absence or reduction of AKK bacteria is negatively correlated with a variety of diseases, including obesity, diabetes, insulin resistance, dyslipidemia, hepatic steatosis, intestinal inflammation, response to tumor immunotherapy, periodontitis, and neurodegenerative diseases.

- **Intestinal wall integrity:** By strengthening the mucus layer, Akkermansia muciniphila helps maintain a healthy intestinal barrier, reduces intestinal permeability, and prevents the invasion of harmful substances and pathogens.
- **Metabolic regulation:** Associated with lower body weight, improved lipid metabolism, and increased levels of intestinal fatty acid oxidation, it may help prevent or treat obesity and type 2 diabetes
- **Immune modulation:** Akkermansia muciniphila may improve local and systemic immune responses by modulating the activity of immune cells in the intestinal mucosa.
- **Anti-inflammatory effects:** It is associated with reducing the levels of certain inflammatory markers and may help combat chronic inflammatory states.
- **Cardiovascular health:** By influencing cholesterol metabolism and reducing the formation of atherosclerotic plaques, it may help reduce the risk of cardiovascular disease.
- **Gut microbiota balance:** It may promote the diversity and balance of the gut microbiota through interactions with other gut microbes.

Application scenarios

Application areas	Scientific basis	Representative strains/products	Maturity
Weight Management	Nature Medicine RCT (2026): Preventing Weight Loss Rebound	MucT (Pasteurized Inactivated)	★★★★★
Metabolic syndrome	Improve insulin sensitivity, lower blood lipids, and intervene in MASLD	AKK-WST01、Akk11	★★★★
GLP-1 drug synergy	Enhances therapeutic efficacy and prevents rebound after drug withdrawal (mouse model)	AKM Lab-01®	★★★
Inflammatory bowel disease	In combination with infliximab, it promotes intestinal mucosal healing (in Phase IV clinical trials)	—	★★★
Tumor Immunology	Enhancing anti-PD-1 efficacy (preclinical)	—	★★
Neurodegenerative diseases	Improve cognitive deficits and extend lifespan (animal models)	—	★★
Healthy aging	Improve muscle strength and regulate inflammatory aging in the elderly	HB05P (Pasteurized Inactivated)	★★★

04. Major Global Research Breakthroughs and Industry Trends of AKK Bacteria

Latest major global research breakthroughs (2025-2026)

4.1 Weight Loss Maintenance – A Milestone Discovery in Nature Medicine (May 2026)

On May 13, 2026, *Nature Medicine* published a landmark randomized controlled trial demonstrating that AKK supplementation can effectively prevent weight regain after weight loss and even help with sustained weight loss. This study was conducted jointly by Maastricht University and Wageningen University. The research has been hailed by the industry as a "completely new solution" in the field of weight loss intervention, directly addressing the most challenging issue in obesity treatment: weight regain.

4.2 Combination therapy with GLP-1 drugs – synergistic effect and prevention of weight regain (2026)

A study published in Cell & Bioscience in January 2026 is the first to explore the combined use of AKK bacteria and smegglutinin. This direction is becoming one of the most commercially promising application scenarios in the "post-smegglutinin era".

4.3 Precision Probiotics – Baseline Abundance Determines Therapeutic Effect (April 2026)

A phase II clinical trial of the AKK-WST01 strain revealed a key finding: the efficacy of AKK bacteria is highly dependent on the baseline abundance of AKK in the patient's gut. This discovery signifies that AKK bacteria are moving from "broad-spectrum probiotics" to "precision intervention," driving the development of personalized probiotic treatment strategies.

4.4 IBD combination therapy – Crohn's disease intestinal mucosal healing (2026)

A prospective, randomized, controlled phase IV clinical trial (NCT07415473) conducted by a Chinese team is exploring the combination of AKK bacteria and infliximab for the treatment of Crohn's disease. This study expands the clinical application of AKK bacteria from the field of metabolism to the field of inflammatory bowel disease for the first time.

4.5 Neurodegenerative diseases—New evidence from animal models

Animal studies in 2026 showed that *AKK* bacteria improved cognitive deficits in Alzheimer's disease models in mice and prolonged the survival of ALS models in mice by regulating tryptophan metabolism. Furthermore, bacterial vesicles derived from *AKK* were found to cross the blood-brain barrier and play a protective role in a smoking-induced cognitive impairment model. These findings open the door to expanding the application of *AKK* bacteria from the gut-metabolism axis to the gut-brain axis.

4.6 Tumor Immunotherapy – Enhancing Anti-PD-1 Efficacy

Preclinical studies have found that AKK bacteria significantly enhance the anti-tumor effect of αPD-1 therapy in gastric cancer by driving CD8+ T cell infiltration and activation in the tumor microenvironment, providing new evidence for probiotics as an adjunct to tumor immunotherapy.

Industry Trends:

Globalization, Ecologicalization, Precision

Globalization: China has become a major producer and supplier of AKK strain raw materials, with products exported to more than 60 countries and regions in Europe and America. Chinese companies' strains have entered mainstream market systems such as the EU (Danone acquired TAC), the US (GRAS certification), and Germany (DSMZ collection).

Ecological approach: AKK bacteria are being used in combination with GLP-1 drugs and with Lactobacillus acidophilus and other bacteria to build a synergistic ecosystem of "microbial ecology + drugs".

Precision: Individualized intervention strategies based on baseline AKK abundance are emerging, indicating that a precision probiotic business model with a closed-loop "test-supplement-evaluation" system will gradually take shape.

05. Latest global compliance progress of AKK bacteria

001 EU

EU – A Global Pioneer

In 2021, the European Food Safety Authority (EFSA) approved pasteurized inactivated AKK bacteria (strain ATCC BAA-835) as a novel food product, making it the world's first approved AKK bacteria product.
In September 2025, EFSA issued further safety advice, expanding the applicable population for pasteurized AKK bacteria to adolescents aged 12–18 years: up to 2.1 × 10^{10} cells/day for 12–14 years and up to 3.0 × 10^{10} cells/day **for 14–18 years.**

Key constraints:

*EFSA explicitly stated that “there is limited available data and a lack of long-term safety evidence.”

*AKK bacteria are not included in the EU's "Presumed Safety List (QPS)," and related products must be strictly labeled as "non-live bacteria preparation" to distinguish them from traditional qualified probiotics.

***Only the pasteurized form is approved**; the live form is not permitted.

05. Latest global compliance progress of AKK bacteria

002 USA

United States - Multiple Certifications under the GRAS System

The United States has accepted multiple AKK strains through the GRAS (Generally Recognized As Safe) certification system.
AKK PROBIO® – the world's first AKK strain to receive GRAS certification for both active and inactivated forms.

Muen Bio AKM Lab-01® – Self-GRAS certified.

AKK ONE – Self-GRAS certified.
Enterobiome EB-AMDK19——It has obtained Self-GRAS certification, and the first products will be available in the United States through Amazon at the end of 2025.

* It is important to note that the FDA's official GRAS certification and the Self-GRAS pathway differ in legal effect: the former requires an FDA "no objection" letter, while the latter allows companies to launch their products after organizing expert evaluations and retaining relevant documents.

003 China

China – A Key Step Towards Compliance

Milestone Event: On November 14, 2025, the National Health Commission officially accepted the application for "Inactivated Akkermansia muciniphila YGMCC2645" as a new food ingredient. This is the first compliant application for Akkermansia muciniphila in China, marking a substantial step forward in the legalization of Akkermansia muciniphila in the country.

Current compliance status:
AKK bacteria have not yet obtained any licenses in China for new food ingredients, health food ingredients, food additives, or pharmaceuticals.
The products are mainly sold through cross-border e-commerce channels. Raw materials are produced in China and exported overseas, while finished products are then shipped back to China.

Industry insiders have warned that some products are entering the market through bonded warehouses under the guise of "inactivated bacteria," but their advertising emphasizes "live bacteria efficacy," which violates the actual approved usage of the raw materials.

004 South Korea

South Korea – the world’s first functional certification

Enterobiome's inactivated AKK strain EB-AMDK19 has been approved by the Korean Ministry of Food and Drug Safety, becoming the world's first officially recognized functional ingredient of AKK bacteria for improving respiratory health (related to cough symptoms).

The product was launched in South Korea through Dong-A Pharmaceutical and promoted in the United States through Amazon.

05. Latest global compliance progress of AKK bacteria

005 Global Compliance Progress

Country/Region	Compliance Status	Approval Form	Remark
EU	✅ New types of food	Pasteurization	The first batch will be launched in 2021, and will be expanded to include teenagers in 2025
USA	✅ GRAS/Self-GRAS	Both live and inactivated bacteria are acceptable	Several Chinese companies have obtained GRAS certification for their strains
South Korea	✅ Functional raw materials	Inactivated bacteria	The world's first to receive official functional certification
China	🔄 New food ingredients are being accepted	Inactivated bacteria (accepted)	The first case was accepted in November 2025; currently, cross-border e-commerce is the main sales channel
Japan	🔄 Review in progress	—	Still under regulatory review

In 2026, the China Food and Drug Enterprises Quality and Safety Promotion Association initiated five group standards, including the "Evaluation Guidelines for the Effects of Ekkermansia on Weight Management," which were drafted under the leadership of Aurevita (Shanghai) Health Technology Co., Ltd., to promote the standardization of the industry's evaluation system.

05. Latest global compliance progress of AKK bacteria

006 Add dosage/form

Commonly used dosage in clinical studies

strains/products	crowd	dose	cycle	Key findings
Parvovirus inactivation AKK MucT®	Overweight/obese adults with metabolic syndrome	1×10^{10} cells/day	12 weeks	Improve insulin sensitivity and reduce weight
Parvovirus inactivation HB05P	≥60 years old elderly people (n=100)	1×10^{10} cells/day	12 weeks	Significantly increased peak torque of the knee extensor muscles (p=0.01), and improved muscle strength
live bacteria Akk11	Obese subjects aged 18–65（n=102，BMI 28–35）	1×10^{10} AFU/day	12 weeks	Weight and BMI decreased, body fat percentage and visceral fat index decreased significantly
live bacteria AKM Lab-01	Overweight/obese people	Clinical trials in progress	—	Weight loss effect and safety evaluation
巴氏灭活AKK	Adults recovering from sepsis in the ICU	Clinical trials in progress	—	Intended to evaluate the effect of rehabilitation promotion

Official Recommended/Permitted Dosage

Regulatory agencies/regions	Recommended/Permissible Dosage
EU EFSA (Adult)	≤3.4×10^{10} cells/day (pasteurization)
EU EFSA (12–14 years old)	≤2.1×10^{10} cells/day
EU EFSA (14–18 years old)	≤3.0×10^{10} cells/day
Mainstream dose in clinical studies	1×10^{10} cells/day (live or inactivated)

Live bacteria vs. inactivated bacteria: Form selection

The functional equivalence of live bacteria and inactivated AKK is a major scientific highlight: multiple studies have shown that both live bacteria and pasteurized inactivated AKK bacteria have good safety when taken orally at a dose of 1×10^{10} cells/day, and their metabolic improvement effects are comparable.

Features	live bacteria	Inactivation (pasteurization)
stability	Anaerobic bacteria require special processing for protection	Stable, can be stored at room temperature
Transport conditions	Requires cold chain logistics, high cost	Convenient transportation and low cost
Security	There is a potential risk of infection (in immunocompromised individuals)	Superior safety, no risk of infection
Regulatory approval	US GRAS system	Both the EU and the US have approved it
Applicable Scenarios	Capsules, functional foods	Capsules, beverages, snacks, and other products in multiple scenarios