Global
Market Access Compliance

2026

Data Cutoff:
April 2026 · Based on official releases and authoritative industry reports

4UNUTRA

THREE PATHWAYS EVOLVING

[GRAS] • [NDI] • [ODI]

What we're observing

1 GRAS self-affirmed reforms in progress

2 NDI guidance under continuous update

3 ODI list being documented

“ ”

Pathway selection benefits from early consideration. We can help you assess which route aligns with your timeline and ingredient profile.

What this means for your planning

3-5 YEARS

IS THE INDUSTRY CONSENSUS TIMELINE FOR NEW HEALTH CLAIMS

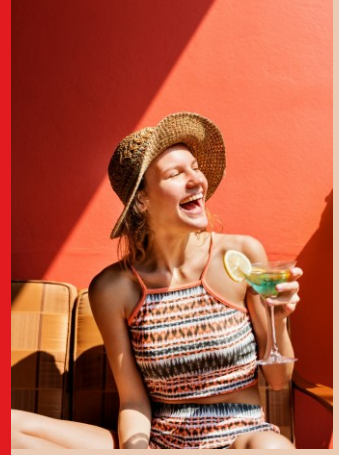
What we're observing

70%+ of health claims rejected

2000+ botanical claims pending

Novel food approval: **2-3** years average

QPS list regularly updated



SECTION TWO EU EFSA

"If your strategy requires new claims, early planning is essential. Using existing approved claims can offer a faster route. We can help you evaluate the options."

What this means for your planning

TWO TRACKS

REGISTRATION VS FILING

What we're observing

1 Filing eligible 24 nutrients + 10 non–nutrients

2 Ginseng/American ginseng/reishi now eligible for filing

3 CoQ10/Melatonin/ Fish oil added to filing

4 First new function approved: helps maintain bone/joint health

SECTION THREE CHINA SAMR

"Choosing ingredients on the filing list can offer a faster track. New ingredients or functions require the registration route. We can help you assess which path fits your product profile."

What this means for your planning

THREE TIERS

[FOSHU] [FNFC] [FFC]

2026 new rules in effect

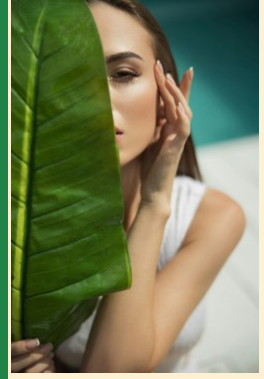
FFC novel ingredients

120 business days review

GMP mandatory for natural extracts

Health harm reports

mandatory immediately



SECTION FOUR JAPAN CAA

"Regular ingredients remain on a faster track via FFC."

"Novel ingredients benefit from planning 6+ months."

What this means for your planning

SECTION FIVE [Industry Estimate]

GLOBAL COMPLIANCE TIMELINE

USA

Fastest Path

NDI notification: 6–12 months

Longer Path

Novel ingredient + clinical: 2–3 years

CHINA

Fastest Path

Within filing: 6–12 months

Longer Path

New ingredient registration: 2–3 years

EU

Fastest Path

Use existing claims: direct market entry

Longer Path

New health claim: 3–5 years

Japan

Fastest Path

Regular ingredient FFC: 60 business days

Longer Path

Novel ingredient FFC: 120 business days

SECTION SIX

Compliance as part of your product strategy

CONSIDERATIONS FOR YOUR PLANNING

#1

Define your target markets first

different markets, different pathways.

Explore compliance options early

some paths offer faster entry.

#2

#3

Factor timing and budget into your roadmap

early planning helps.

Consult professionals when needed

we're here to help navigate.

#4

SECTION SEVEN

DATA SOURCES & DISCLAIMER

Sources consulted

FDA.gov · EFSA · China SAMR · Japan CAA

SupplySide 2026 · Lexology · Food Supplements Europe

China Market Regulation News 2026 · Foodmate Law Summary

Medical Japan Industry Insights · Industry consensus reports

Important note

This document is based on publicly available information as of March 2026, for business reference only. Regulations may change. We recommend consulting official sources or professional advisors for specific compliance requirements applicable to your products and markets.

4UNUTRA

For more information, please feel free to contact us.

4Unutra(Hainan) Co., Ltd

Home:www.4nuntra.com

Email:info@4unutra.com

Te1: +86 0898 6537 8036

Phone:+86 193 8998 4020

No.181 Xingyang Avenue, Jiangdong New District,Haikou,Hainan, China