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“EU, Novel Food and CBD – a never ending story or finally a happy end?”

Seven years of regulatory uncertainty — and what happens next

CB Expo 2026

17 September 2026 | Dortmund

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European Union (EU) • Cannabidiol (CBD)

2017–2019: The CBD Gold Rush

HUNDREDS OF NEW BRANDS

CBD oils • capsules • gummies • foods • beverages • cosmetics

$416m

estimated European CBD market by end of 2019

$1.7bn

2019 forecast for 2023

€/$ BILLION MARKET EXPECTATIONS

Then came January 2019.

2019 figures: contemporary Brightfield Group reporting; historical expectations, not a realised time series.

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January 2019: The Novel Food Turning Point

BEFORE 2019

Cannabis sativa L. and certain traditional hemp foods had a recognised history of consumption.

The catalogue wording distinguished traditional hemp foods from cannabinoid-enriched products (natural content).

JANUARY 2019

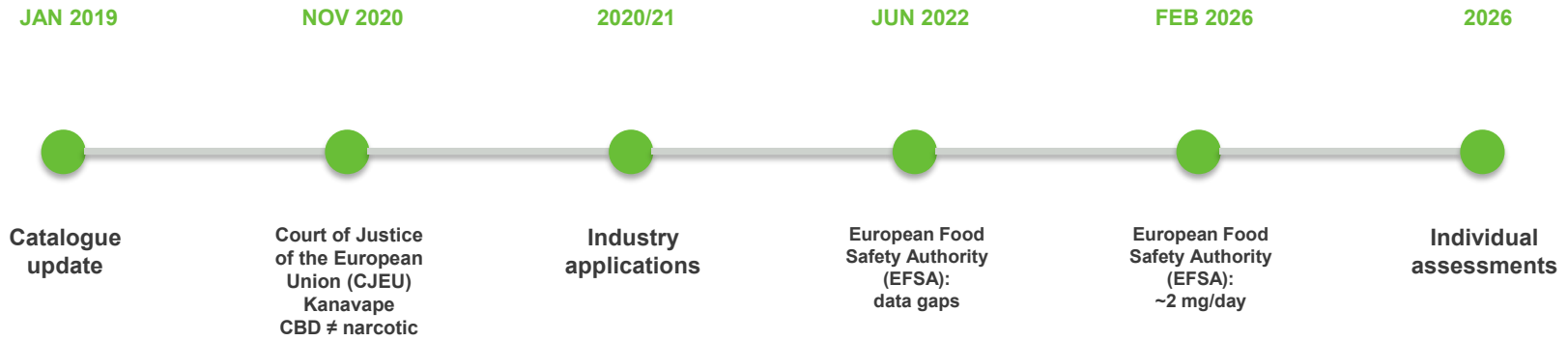
The Commission updated the Novel Food Catalogue so cannabinoid-containing extracts were treated as novel where no significant pre-1997 consumption could be shown.

The Novel Food Catalogue is not legally binding —
but the 2019 change fundamentally altered enforcement practice across Europe.

Sources: European Commission Novel Food Catalogue; Regulation (EU) 2015/2283.

2019–2026

Seven Years in Regulatory Limbo



Market presence continued, albeit on a low level.
EU authorisation did not.

Sources: Commission Novel Food Catalogue; CJEU C-663/18; EFSA statements 2022 and 2026.

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EFSA CBD Novel Food Applications — Procedural Status

DOSSIERS

200+

entered / recorded in the process

SUITABILITY CHECK

3

dossiers

RISK ASSESSMENT

17

15 extracted CBD
+ 2 synthetic CBD

OUTCOME

3

negative opinions

These figures are presented as procedural status figures — not as a linear funnel.

A large application pipeline — but still no authorised CBD Novel Food in the European Union.

Source: EFSA, Risk Assessment of CBD as a Novel Food, webinar 21 April 2026, slide 10.

THE ECONOMICS OF A JOINT APPLICATION

European Industrial Hemp Association (EIHA): Pooling the Cost of Novel Food

INDIVIDUAL ROUTE

€350k–€500k

EIHA's original estimate for one company registering a single product under the Novel Food framework.

EIHA CONSORTIUM

up to €3.5m

Collective budget for the relevant toxicological studies on cannabidiol (CBD) and tetrahydrocannabinol (THC).

INGREDIENT RANGE

4 categories

Isolate • Gold • Regular • Raw

EIHA planned testing around the 'worst toxicological case' among the products submitted.

MODEL **Pool contributions → commission GLP/OECD toxicology studies → EIHA projects GmbH manages the resulting protected data / rights for participating members.**

2026 STATUS EFSA now assesses each CBD Novel Food application on the data in its individual dossier.

Sources: EIHA Novel Food Consortium; EIHA 2020 consortium information; EFSA, 9 Feb & 21 Apr 2026.

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The Dose Gap — and Why EFSA Arrived at 2 mg/day

EFSA

≈ 2 mg/day

Provisional safe intake
0.0275 mg/kg bw/day

Applies only to ≥98% CBD food supplements meeting EFSA's stated conditions.

CBD isolate can then be used in edibles and as „water soluble CBD"

UK FOOD STANDARDS AGENCY (FSA)

10 mg/day

Maximum acceptable daily intake / consumer advice for healthy adults.

Final **Decision** at 9/16/2026???

EIHA DOSSIER

17.5 mg/day

Proposed acceptable daily intake (ADI) for Natural CBD Isolate in oil.

HOW EFSA DERIVED THE UNCERTAINTY FACTOR 400

$BMDL_{10}$ 11 mg/kg bw/day ÷ **100** (inter- + intraspecies) × **2** (subchronic → chronic) × **2** (other organ-system uncertainties) **= UF 400 → 0.0275 mg/kg/day**

SAFETY NOT ESTABLISHED

<25 years
Pregnant / lactating
Concurrent medication

EFSA reference point: liver toxicity (female rats). Additional factor addresses possible lower-dose effects in neurological, psychiatric, reproductive, neurodevelopmental and immune endpoints.

Source: EFSA Journal 2026;24:e9862, sections 5–7; EFSA news, 9 Feb 2026.

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When Could the First CBD Novel Food Be Authorised?

FEB 2026

EFSA sets a provisional safe intake:

≈ 2 mg/day

Not an authorisation.

→

EFSA

Individual dossier risk assessment

Statutory period: up to 9 months*

Additional data can extend the clock.

→

POSITIVE OPINION?

Only if the specific CBD ingredient, specifications and proposed conditions of use are considered safe.

→

COMMISSION

Draft implementing act / Union List update

Statutory period: up to 7 months after EFSA opinion.

EU

AUTHO RISED

EARLIEST REALISTIC WINDOW

2027–2028*

*Scenario, not an announced EFSA or Commission date.

2 mg/day is the current safety benchmark for defined ≥98% CBD food supplements — not a generic CBD authorisation.

The actual timing depends mainly on dossier completeness and whether EFSA requests further toxicological / human data.

Legal basis: Regulation (EU) 2015/2283, Arts. 11(1), 11(4) and 12(1). EFSA CBD statement, 9 Feb 2026.

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CBD in Cosmetics: The Positive Signal

26 March 2026

CBD

Safe up to

0.19%

in dermal and oral cosmetic products

THC IMPURITY

Delta-9-tetrahydrocannabinol (THC)

up to 0.00025%

BUT: SCIENTIFIC ADVICE

The SCCS assessment concerns pure CBD, excludes inhalation exposure and is scientific advice — not yet a binding statutory concentration limit.

At almost the same time, another EU process was moving in the opposite direction …

Source: SCCS/1685/25. Final advice adopted 26 Mar 2026; published 24 Apr 2026.

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Repr. 1B — A Countdown, but Not Necessarily the End

RAC OPINION
Risk Assessment Committee

Repr. 1B
H360FD + H362

Opinion 6 Mar 2026

→

COMMISSION

Future Adaptation to Technical Progress (ATP)

No binding date yet

→

ART. 15
Reg. (EC) No 1223/2009

General prohibition for carcinogenic, mutagenic or toxic to reproduction (CMR) 1A/1B substances in cosmetics

→

BUT

A statutory derogation is possible if all applicable conditions are met.

WHY THE 2026 SCCS OPINION MATTERS

POSITIVE SAFETY ASSESSMENT

Scientific Committee on Consumer Safety (SCCS): pure CBD considered safe up to 0.19% in dermal and oral cosmetic products.

NOT AN AUTOMATIC EXEMPTION

Article 15 currently requires additional conditions. The existing SCCS advice is highly relevant, but a post-classification / use-specific derogation process may still be required.

Repr. 1B → general Art. 15 prohibition — but a derogation may preserve defined CBD cosmetic uses.

TIMELINE — **RAC opinion Jul 2026** → **ATP 2026/2027*** → **CLP transition ~18 months*** → **Application ~2028/2029***

*Indicative only; the future ATP will set the binding application date.

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Article 15 Derogation: What Would CBD Need to Show?

1 FOOD SAFETY

CBD must comply with the food-safety requirements of Regulation (EC) No 178/2002.

For CBD, this may be the most difficult condition given the current Novel Food / EFSA position.

2 NO ALTERNATIVES

No suitable alternative substance may be available.

This must be documented by an analysis of alternatives for the intended cosmetic function.

3 DEFINED USE

The request must concern a particular use within a product category with known exposure.

Not a blanket authorisation for 'CBD in cosmetics'.

4 SCCS SAFETY

SCCS must find the use safe, considering product exposure, overall exposure from other sources and vulnerable groups.

The 0.19% opinion is a strong starting point.

CURRENT LAW: all four Art. 15(2) conditions are cumulative.

REGULATORY WILDCARD 2025 Commission proposal could simplify Art. 15 derogation requirements; as of Aug 2026, it is not yet current law.

TIMELINE

RAC opinion Jul 2026 → ATP 2026/2027* → CLP transition ~18 months* → Application ~2028/2029*

*Indicative only; the future ATP will set the binding application date.

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Where Are We Now — and Where Could Industry Challenge?

1 NOVEL FOOD

2 mg benchmark

EFSA's provisional safe intake guides dossier-by-dossier assessment. A later authorisation or refusal is a Commission implementing act.

REMEDY / LEVER

EFSA opinion itself: generally preparatory.
Final Commission act: potential Art. 263 TFEU challenge by a directly / individually concerned applicant; national enforcement can also lead to judicial review / Art. 267 reference.

2 COSMETICS / SCCS

0.19% safety opinion

SCCS scientific advice supports a possible Art. 15 derogation, but is not itself a binding exemption from a future CMR prohibition.

REMEDY / LEVER

Focus first on the Art. 15 derogation procedure and evidence: no suitable alternatives, defined use/exposure, SCCS safety; current law also includes food-safety condition.
Challenge normally becomes concrete with a binding Commission measure.

3 CLP / REPR. 1B

RAC opinion → ATP?

RAC opinion is sent to the Commission. Binding harmonised classification arises only through a Commission delegated act / ATP amending Annex VI.

REMEDY / LEVER

RAC stage: scientific / procedural submissions and new-data route.
Final ATP: potential Art. 263 TFEU action against the delegated act, subject to standing; national application may permit Art. 267 review.

KEY LEGAL DISTINCTION: scientific opinions shape the outcome — binding EU acts are normally the main target for judicial review.

Further legal review needed: standing, admissibility, review intensity for scientific assessments, interim relief and the best route for industry associations vs. individual applicants.

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2 mg/day: Is There a Viable Product?

Illustration: 10 ml oil • 5% cannabidiol (CBD)

≈ 500 mg CBD per bottle

÷ 2 mg/day

≈ 250 daily doses

ONE BOTTLE ≈ EIGHT MONTHS (stability?)

PRODUCT

Low-dose / micro-dose formats

ECONOMICS

different consumer expectation

LAW

Final authorisation conditions still matter

Illustrative calculation only. Actual compliance depends on the final Novel Food authorisation, specifications, conditions of use and labelling.

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How Big Is the Market We Are Actually Regulating?

BROAD EUROPEAN CBD MARKET

USD 2.3 bn

2025 estimate

Includes hemp- and marijuana-derived CBD, OTC products, medical / therapeutic applications, pharmaceuticals and topicals.

“Europe” is not identical to the European Union.

CBD CONSUMER HEALTH

USD 825.7 m

Europe, 2024

A narrower consumer-health dataset — but its largest segment is CBD-infused skincare.

Only partly relevant to Novel Food.

CBD NUTRACEUTICALS

USD 0.4–0.8 bn

Europe, 2024

Tinctures, capsules / softgels and gummies.

Closest commercial proxy for the ingestible CBD market — but the source itself reports inconsistent totals.

THERE IS NO ROBUST PUBLIC FIGURE FOR THE EU NOVEL-FOOD CBD MARKET.

Germany illustrates the problem: published 2024 estimates range from USD 17.6 m for a broad CBD dataset to USD 96.5 m for CBD consumer health; CBD nutraceutical estimates are also internally inconsistent.

Sources: Grand View Research: Europe Cannabidiol Market (2025); Europe CBD Oil & Consumer Health (2024); Europe CBD Nutraceuticals (2024); Germany datasets. Commercial estimates use different scopes and methodologies.

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Happy End? Three Questions for the Panel

1. **Will industry invest in EU authorisation if the commercial ceiling is ~2 mg/day?**

2. **Can new data move EFSA materially above 2 mg — and on what timeline?**

3. **If CBD becomes Repr. 1B, can the European CBD cosmetics market survive?**

Never ending story — or finally a regulatory pathway?