

Legal Classification of Kava (*Piper methysticum*) as a Food in the EU

Date: June 23, 2025

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Status: Public Legal Opinion

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1. Executive Summary

This document summarizes the legal assessment of Kava (*Piper methysticum*) in the context of the EU Novel Food Regulation (EU) 2015/2283. The analysis of the historical facts leads to the unequivocal conclusion that Kava is **not to be classified as a Novel Food**.

The body of evidence, supported by official documents, scientific publications, and market data from before 1997, demonstrates a significant history of use of Kava in the European Union before the cut-off date of May 15, 1997. Consequently, Kava is not subject to the authorization requirements of the Novel Food Regulation and can be placed on the market in the EU as a regular food or food supplement, provided it complies with general food law provisions.

2. The Definition of "Novel Food"

The EU Regulation 2015/2283 defines a "Novel Food" as a food that "had not been used for human consumption to a significant degree within the Union before 15 May 1997" ¹. The decisive question, therefore, is whether such a history of use can be proven for Kava.

3. Historical Use of Kava in the EU before 1997

The crucial evidence against a classification as a Novel Food is based on the documented use of Kava as a medicinal product and a commercially available product in Europe long before the cut-off date.

3.1. Official Authorization as a Medicinal Product in Germany

The strongest piece of evidence is the official recognition of Kava by German authorities. As early as 1990—seven years before the cut-off date—the **German Commission E**, a scientific advisory board of the Federal Institute for Drugs and Medical Devices (BfArM), positively assessed the therapeutic efficacy of Kava medicinal products ².

Kava-containing medicinal products were legally authorized in Germany and available in pharmacies under brand names such as "Antares" and "Kavasporal forte." A substance that has undergone a rigorous authorization process as a safe and effective medicinal product cannot, by definition, be a "novel" substance with no history of use.

3.2. Commercial Availability throughout Europe

Commercial distribution was not limited to Germany. A key study by the ETC Group from September/October 1997 documents the market situation at the time, stating:

"In Europe alone, kava extracts are being sold by at least 14 drug companies." ⁴

This statement proves that an established market with at least 14 pharmaceutical companies already existed in Europe at the time of the cut-off date. Such a market presence does not emerge overnight but rather demonstrates years of commercial activity and thus a "use to a significant degree."

4. Legal Precedent and Burden of Proof

Case law, including from the European Court of Justice (ECJ), has established that the burden of proof for the novelty of a food lies with the authority making that claim ⁶. A food business operator does not have to prove that their product is *not* novel. Given the overwhelming evidence of a significant history of use for Kava before 1997, it would be legally almost impossible for an authority to prove the contrary.

5. Conclusion

The legal analysis leads to the unambiguous conclusion that Kava (*Piper methysticum*) is not to be classified as a Novel Food within the meaning of Regulation (EU) 2015/2283. The evidence is overwhelming and includes:

- **Official authorizations as a medicinal product** in Germany before 1997.
- A **positive monograph from the Commission E** as early as 1990.
- The proven **commercial availability** through at least 14 pharmaceutical companies in Europe.

Kava has a clear and well-documented history of use in the EU before May 15, 1997, and is therefore to be treated as a regular food.

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