

# Classification of the aqueous extract of the leaves of *Melissa officinalis* L. as “not novel food”

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Date: 11.05.2026

An application for a preliminary assessment regarding the classification of an aqueous extract of the leaves of *Melissa officinalis* L. in relation to its novel food status was submitted to the Federal Food Safety and Veterinary Office (FSVO).

This foodstuff is a **4:1 aqueous extract from the leaves of *Melissa officinalis* L.**, intended for use in food supplements. The leaves have been consumed to a significant degree by humans for centuries. The use of the leaves for the preparation of herbal teas (aqueous infusions) was also known prior to 1997.

The FSVO examined the submitted documentation and determined the Novel Food status of the aqueous extract of the leaves of *Melissa officinalis* L. In principle, according to the consensus view of the EU Member States, the same status applies to non-concentrated aqueous infusions made from non-novel foods for use as herbal tea. The aqueous extract should therefore be comparable to an aqueous infusion (herbal tea) not only in terms of composition but also in terms of the amount consumed.

The applicant has demonstrated, by means of HPLC analyses, that the composition of the aqueous extract is comparable to that of an aqueous infusion (herbal tea) and that no selective enrichment has been produced. On the basis of the submitted documentation, it can therefore be assumed that the composition of the aqueous extract can be regarded as ‘equivalent’ to aqueous infusions such as herbal tea.

Aqueous extracts of the leaves of *Melissa officinalis* L. are also used as traditional medicinal products. It must therefore be ensured that the dosage of the aqueous extract has no pharmacological effect and is comparable to its use as herbal tea.

The FSVO concludes that the 4:1 aqueous extract of *Melissa officinalis* L. leaves is classified as ‘non-novel’ and therefore does not fall within the definition of novel foods under Article 15 paragraph 1 of the Ordinance on Foodstuffs and Utility Articles (FUAO; SR 817.02). The delimitation from medicaments must be ensured within the framework of self-regulation.

The aqueous extract of *Melissa officinalis* L. leaves 4:1 is therefore not subject to the authorisation requirement for novel foods under Article 17 of the FUAO.