

MAXIMUM THC LIMIT VALUES IN FOOD PRODUCTS IN ITALY: FINALLY, THE IMPLEMENTING DECREE

The Decree of the Italian Ministry of Health adopted on 4 November 2019, which sets the limits of the THC concentration permitted in foodstuff, was published on 15 January 2020 in the Italian Official Gazette (the "**Decree**"; the link to Italian Official Gazette upon which to find the full copy in Italian of the Decree is <https://www.gazzettaufficiale.it/eli/gu/2020/01/15/11/sg/pdf>).

It is a welcome and long overdue implementation measure to Italian Law no. 242 of 2 December 2016 ("**Italian Law 242**").

Background

Italian Law 242 sets forth the rules for the promotion of the cultivation and food chain of hemp in Italy. Article 2 of Italian Law 242 provides that food can be obtained from hemp plants cultivated in accordance with the provisions of Italian Law 242 and produced exclusively in compliance with the rules applicable to the respective sectors. According to Article 5 of Italian Law 242, the maximum level of THC allowed in food products was to be determined by a decree of the Italian Ministry of Health, envisaged to be adopted within six months after the entry into force of Italian Law 242.

The Decree, just published and implementing Italian Law 242, finally brings a modicum of certainty to Italian manufacturers and distributors operating in the permitted hemp cultivation business, following the vague landscape created on 31 May 2019 by ruling no. 30475/19 of the Italian Supreme Court. In this ruling, the Supreme Court held that the sale to the public, for any reason, of products derived from *cannabis sativa* L., including oil, leaves and inflorescences, and resin is a criminal offence unless the products, in practice, have no doping effect, according to the principle of the offensiveness of the conduct. Although the ruling interpreted strictly the provisions of Italian Law 242, it invited the Italian legislator to revisit the legislation and provide a clearer set of rules. This applies especially to the food sector, for which Italian Law 242 expressly requires the Ministry of Health to determine the maximum levels of residual THC allowed in foodstuffs derived from hemp derivatives (other than leaves and inflorescences).

The Decree

The Decree not only provides guidance on THC concentration in foodstuff but also sets out a framework in connection with the various regulations at the EU level. Due to ongoing scientific research, the information provided in the Decree and the limit values will be updated, from time to time, on the basis of new research findings.

Key issues

- Clarity, at last, on the maximum limit values of THC in certain food products derived from *cannabis sativa*
- Uncertainty going forward in the field of hemp plant cultivation

- **Applicability and definition of hemp:** the Decree lays down the values of the total maximum permissible THC concentrations in foodstuffs derived from hemp. The Decree expressly defines hemp as the plant of "*cannabis sativa L.*", which is consistent with the requirements of art. 32, para. 6 of EU Regulation 1307/2013.
- **Hemp-derived food products:** hemp-derived products are described under Annex I to the Decree. For the purposes of the Decree, hemp-derived food products are only hemp seeds (including shredded, broken and ground seeds) of, and flour and oil obtained from, hemp seeds.
- **Maximum levels of THC:** Annex II of the Decree lists the precise values of THC concentration allowed in food products, as shown in the table below.

Maximum THC Limit Values

The maximum THC limit values are defined as the sum of the concentrations of the substance (-)-trans- Δ^9 -THC (*) and the inactive acid precursor (Δ^9 -THCA-A (**).

(*) (-)-trans- Δ^9 -THC: of the four possible stereoisomers, it is the only one existing in nature;

(**) the inactive acid precursor (Δ^9 -THCA-A) represents 90% of the sum of the concentrations of the substance Δ^9 -THC and of the two inactive acid precursors (Δ^9 -THCA-A e Δ^9 -THCA-B).

Table. Maximum THC Limit Values

Food products	Maximum THC Levels (mg/kg)
Hemp seeds, flour obtained from hemp seeds	2.0
Oil obtained from hemp seeds	5.0
Supplements containing hemp-derived food products	2.0

- **Sampling and analysis methods:** reference to the European legislative framework will guarantee standard sampling and monitoring activities as to the presence of THC in food products.
- **European coordination:** goods sold lawfully in another EU Member State, in Turkey or in an EFTA State signatory of the EEA agreement are within the scope of application of the Decree.

What next?

Is the newly-published Decree a sign that the Italian legislature will focus its attention on regulating this matter in more detail? The Decree limits its provisions and scope of application to a specific sector of products connected with hemp and its derived products, an area of growing attention for business operators at the national and international level.

Certainly, there is a growing request from the Italian industry for a clear set of rules governing hemp and hemp-derived products, especially after the restrictions set by the Supreme Court in May 2019.

A return to hemp cultivation in Italy may be an opportunity for farms to exploit innovation and diversity in their range of products, and could foster national and international investment, as has been seen overseas and in other European countries.

Clifford Chance will continue to monitor developments in this area and can advise on the implications for your business. Please get in touch with your usual Clifford Chance contact or the authors of this briefing note for specific advice.

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