

Italy

Cannabis sativa L. in Foodstuffs: the Italian Case and the Need for EU Harmonised Limits for THC Unavoidable Contamination

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The following report aims at a short description of the plant species *Cannabis sativa L.* from a scientific perspective, in order to provide key aspects related to botanical classification, secondary metabolism, phytochemistry and breeding; highlighting the legal uncertainties linked to the lack of harmonized regulatory frameworks at EU level for hemp and cannabis-derived foods.

I. Some Scientific Insight on *Cannabis sativa L.* Plant Species

Cannabis sativa L. is one of the phytochemically best-characterized plant species with several hundreds of secondary metabolites identified.¹ Large variations in secondary metabolite composition and content occur among plants of the same population.

Among other identified compounds, cannabinoids are terpenophenolic compounds classified according to their source (i.e. natural or phyto-cannabinoids, chemically-engineered or synthetic cannabinoids, and human endocannabinoids or human

metabolic by-products). Their chemical structure can be described as a terpene unit combined to a resorcinol moiety with alkyl substitution, or as a benzopyran ring system; several distinct structural-types have been isolated.²

The quantitative content of phytocannabinoids among different cannabis accessions is variable up to four orders of magnitude.³ Phytocannabinoids are contained at the highest level in reproductive tissues (i.e. flowers and inflorescences), followed by leaves. Stems,⁴ roots and seeds present lower or practically undetectable levels of contents.

The species classification is challenging because of cultural, geographic dispersion and humans' selection over thousands of years. The genre appears to be best described as including one species, whose intrinsic variations, caused by the artificial selection related to the final purpose of cultivation, are followed by naturalization, cross-breeding and characters' recombination. This complex variation pattern leads to a number of morpho-physiologic and biochimic extreme forms together with a large and continuous range of intermediates.⁵

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1 Salvatore Casano, Gianpaolo Grassi and Marco Michelozzi et al., "Variations in Terpene Profiles of Different Strains of *Cannabis sativa L.*", *XXVIII International Horticultural Congress on Science and Horticulture for People (IHC2010): A New Look at Medicinal and 925* (2010), at pp. 115-121; Giovanni Appendino, Guisepina Chianese and Orazio Tagliatalata-Scafati, "Cannabinoids: Occurrence and Medicinal Chemistry", *Current medicinal chemistry* (2011), 18(7), at pp. 1085-1099.

2 Jaroslav Pec, Isvett Josefina Flores-Sanchez and Young Hae Choi et al., "Metabolite Analysis of *Cannabis sativa L.* by NMR Spectroscopy", *Functional Genomics* (2012), at pp. 363-375; Isvett

Josefina Flores-Sanchez and Robert Verpoorte, "Secondary Metabolism in Cannabis", *Phytochemistry reviews* (2008), 7(3), at pp. 615-639.

- 3 Ann F. Vogelmann, Jocelyn C. Turner and Paul G. Mahlberg, "Cannabinoid Composition in Seedlings Compared to Adult Plants of *Cannabis sativa*", *Journal of Natural Products* (1988), 51(6), at pp. 1075-1079; Kálmán Szendrei, "Cannabis as an Illicit Crop: Recent Developments in Cultivation and Product Quality", *Bulletin on Narcotics* (1997), 49(1/2), at pp. 1-22.
- 4 Pietro Cappelletto, Marina Brizzi and Francesco Mongardini et al., "Italy-grown Hemp: Yield, Composition and Cannabinoid Content", *Industrial Crops and Products* (2001), 13(2), pp. 101-113.
- 5 Christine M. Wilmot-Dear, "FSA Contributions 14", *Bothalia* (1999), 29(2), pp. 249-252; William A. Emboden, "The Genus Cannabis and the Correct Use of Taxonomic Categories", *Journal of Psychoactive drugs* (1981), 13(1), pp. 15-21; Richard E. Schultes, "Random Thoughts and Queries on the Botany of Cannabis", in C.R.B. Joyce and S.H. Curry (ed.), *The Botany and Chemistry of Cannabis* (London: J. & A. Churchill 1970), pp. 39-48.

To overcome the problem of cannabis classification and to distinguish⁶ hemp-types mainly grown for textile or seed production (industrial hemp or hemp) from the most widely disseminated drug-types with high THC contents (medicinal cannabis, recreational cannabis or marijuana) used as an illicit drug⁷ and for therapeutics⁸, a simple and useful classification is based on qualitative and quantitative contents of two major cannabinoids: Δ^9 -tetrahydrocannabinol (THC) and cannabidiol (CBD). So far, it has been possible to distinguish three main chemical phenotypes (chemotypes): “intoxicant”, “semi-intoxicant” and “non-intoxicant”. Based on the analytical values, a single plant or open field cultivation can be positioned within a chart that defines its chemical phenotype (Figure 1).⁹

Many factors affect the phytocannabinoids biosynthesis and bioaccumulation during growth, harvest and post-harvest treatments.¹⁰ Cannabinoid quantity and their ratio (i.e. THC/CBD) is variable according to tissue type and chemical phenotype;¹¹ it

is closely dependant on growing conditions¹² and related to agricultural and collection practices.¹³ Moreover, several published research papers highlight how cannabinoid contents are influenced by soil physicochemical properties¹⁴ (i.e. macro-micronutrient content and availability).

Thus, biometric parameters (i.e. canopy, root system, growth, development, assimilation, and assimilate partitioning), growing conditions and genetic homogeneity¹⁵ are essential to obtain therapeutic grade products, but also to standardize open field productions¹⁶. From a genetic point of view, drug-types and hemp-types present wide metabolic differences¹⁷ distributed across the genome¹⁸.

Cannabis seeds have been extensively described in the scientific literature, and some traces of cannabinoids has been occasionally found in seed-derived oils, mainly due to external contaminants such as resin adherent to the seed or plant parts' residues.²⁰ Comprehensive genetic and cannabinoid profile screenings are required in order to identify chemical phenotype vari-

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- 6 Tom Decorte, “Fibre Hemp and Marihuana: Assessing the Differences Between Distinct Varieties”, *Working Paper Series on Policing* (2011), 38, pp. 1-16.
- 7 UNODC, “World Drug Report 2015” (May 2015), Austria; EMCDDA, “Annual Report on the State of the Drugs Problem in Europe” (2012), Lisbon.
- 8 Maurizio Bifulco and Simona Pisanti, “Medicinal Use of Cannabis in Europe”, *EMBO Reports* (2015), e201439742; Sabina Giacompo, Giuseppe Mandolino and Maria Galuppo et al., “Cannabinoids: New Promising Agents in the Treatment of Neurological Diseases”, *Molecules* (2014), 19(11), pp. 18781-18816; Eduardo Tibiriça, “The Multiple Functions of the Endocannabinoid System: a Focus on the Regulation of Food Intake”, *Diabetology & Metabolic Syndrome* (2010), 2(5).
- 9 Etienne P.M. De Meijer, “The Chemical Phenotypes (Chemotypes) of Cannabis”, *supra* note 10, p. 89; Small E. and Beckstead H.D., “Common Cannabinoid Phenotypes in 350 stocks of Cannabis”, *Lloydia* (1973), 36, pp. 144-165; Small E. et al., “The Evolution of Cannabinoid Phenotypes in Cannabis”, *Economic Botany*, 1975, 29, pp. 219-232; Small E. et al., “A Numerical Taxonomic Analysis of Cannabis with Special Reference to Species Delimitation”, *Systematic Botany* (1976), 1, pp. 67-84; E. Small and A. Cronquist, “A Practical and Natural Taxonomy for Cannabis”, *Taxon* (1976), 25, p. 405.
- 10 Desmond Corrigan, “The Pharmacology of Cannabis: Issues for Understanding Its Use”, *EMCDDA MONOGRAPHS* (2008); Ethan B. Russo, “Constituents, History, International Control, Cultivation, and Phenotypes of Cannabis”, in Roger Pertwee (ed.), *Handbook of Cannabis* (Oxford: Oxford University Press 2014), p. 1.
- 11 Etienne De Meijer, “The Chemical Phenotypes (Chemotypes) of Cannabis”, in Roger Pertwee (ed.), *Handbook of Cannabis* (Oxford: Oxford University Press 2014), p. 89.
- 12 Remco Muntendam, Nizar Happyana and Tjalling Erkelens et al., “Time Dependant Metabolomics and Transcriptional Analysis of Cannabinoid Biosynthesis in *Cannabis sativa* var. Bedrobinol and Bediol Grown under Standardized Condition and with Genetic Homogeneity”, *Online International Journal of Medicinal Plants Research* (2012), 1(2), pp. 31-40.
- 13 Willem K. Scholten, “The New European Union Good Agricultural and Collection Practice Rules: Are Good Practices Good Enough if they Do Not Result in Batch-to-Batch Consistency?”, *Drug Information Journal* (2003), 37(3), pp. 321-327.
- 14 Alan Haney and Benjamin B. Kutscheid, “Quantitative Variation in Chemical Constituents of Marihuana from Stands of Naturalized *Cannabis sativa* L. in East Central Illinois”, *Economic Botany* (1973), 27, pp. 193-203; H. Kaneshima, M. Mori and T. Kitsuata, “Studies on Cannabis in Hokkaido (part 6). The Dependence of Cannabis Plants on Iron Nutrition”, *Hokkaidoritsu Eisei Kenkyussho* (1973), 23, pp. 3-5; R.P. Latta and B.J. Eaton, “Seasonal Fluctuations in Cannabinoid Content of Kansas Marijuana”, *Economic Botany* (1975), 29, pp. 153-163; C.B. Coffman and W.A. Genter, “Cannabinoid Profile and Elemental Uptake of *Cannabis sativa* L. as Influenced by Soil Characteristics”, *Agronomy Journal* (1975), 67, pp. 491-497; C.B. Coffman and W.A. Genter, “Responses of Greenhouse-grown *Cannabis sativa* L. to Nitrogen, Phosphorus and Potassium”, *Agronomy Journal* (1977), 69, pp. 832-836.
- 15 George D. Weiblen, Jonathan P. Wenger and Kathleen J. Craft et al., “Gene Duplication and Divergence Affecting Drug Content in *Cannabis sativa*”, *New Phytologist* (2015), pp. 1241-1250.
- 16 Alessandro Zatta, Andrea Monti and Gianpietro Venturi, “Eighty Years of Studies on Industrial Hemp in the Po Valley (1930–2010)”, *Journal of Natural Fibers* (2012), 9(3), pp. 180-196.
- 17 Teresa Docimo, Roberto Consonni and Immacolata Coraggio et al., “Early Phenylpropanoid Biosynthetic Steps in *Cannabis sativa*: Link between Genes and Metabolites”, *International journal of molecular sciences* (2013), 14(7), pp. 13626-13644.
- 18 Jason Sawler, Jake M. Stout and Kyle M. Gardner et al., “The Genetic Structure of Marijuana and Hemp”, *PLoS one* (2015), 10(8), e0133292.
- 20 Welling M.T. et al., “Characterisation of cannabinoid composition in a diverse *Cannabis sativa* L. germplasm collection”, *Euphytica* (2015), pp. 1-13.

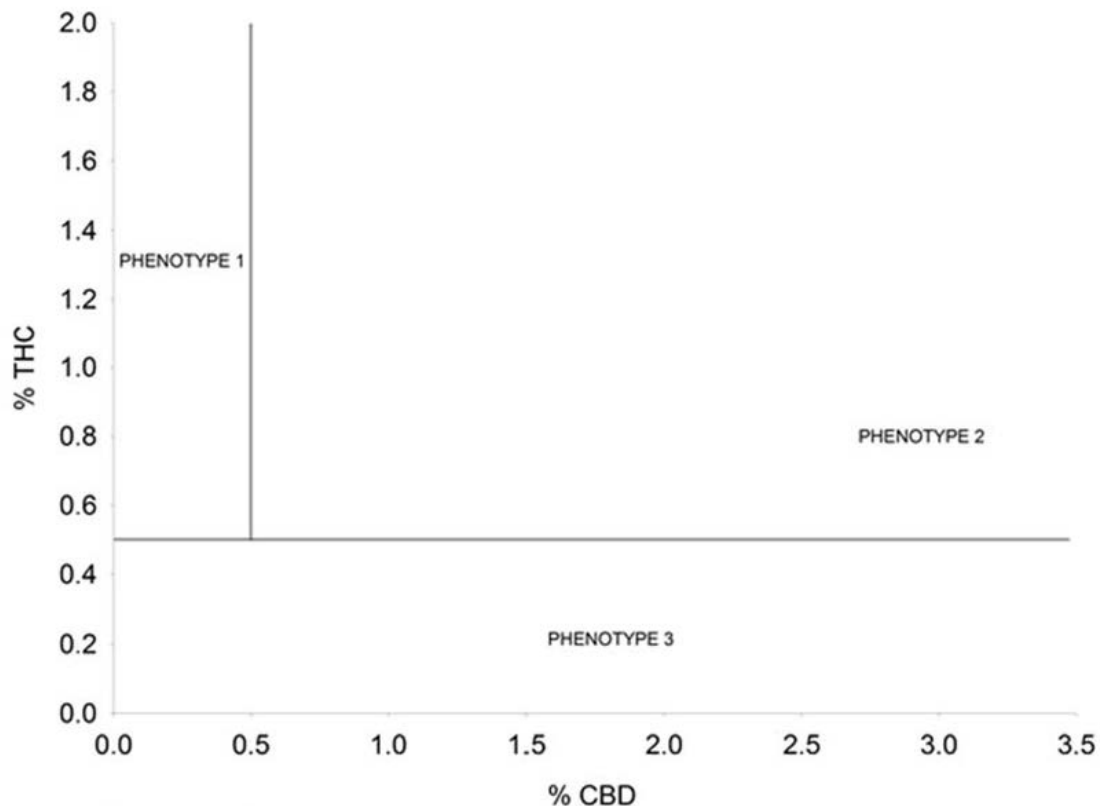


Figure 1. Classification areas based on two major phytocannabinoid contents.

Phenotype 1 – Psychotropic (drug-type), intoxicant chemical phenotype

Phenotype 2 – Semi-intoxicant or intermediate chemical phenotype

Phenotype 3 – Non-psychotropic (hemp-type), non-intoxicant chemical phenotype

Source: Small E., “Evolution and Classification of *Cannabis sativa* (Marijuana, Hemp) in Relation to Human Utilization”, *The Botanical Review*, 2015, 81(3), pp. 189-294.

ants for specific applications and to explore more in detail the relationship between cannabis chemotypes and genotypes. **NOTE 19a NICHT GEFUNDEN** Hemp-type seeds (HS) and derived oils (HSO)²¹ have been ad-

dressed as feed²² and functional food, with relevant dietary supplements and preventive applications.²³

The THC content in foods and cosmetics derived from HS and HSO does not cause unintentional psy-

21 J.C. Callaway and T.T. Laakkonen, “Cultivation of Cannabis Oil Seed Varieties in Finland”, *Journal of the International Hemp Association* (1996).

22 Erin M. Goldberg, Naveen Gakhar and Donna Ryland et al., “Fatty Acid Profile and Sensory Characteristics of Table Eggs from Laying Hens Fed Hempseed and Hempseed Oil”, *Journal of Food Science* (2012), 77(4), pp. S153-S160.

23 J.C. Callaway, “Hempseed as a Nutritional Resource: An Overview”, *Euphytica* (2004), 140(1-2), pp. 65-72; Kenneth Jones, “Nutritional and Medicinal Guide to Hemp Seed”, *Rainforest Botanical Laboratory* (Canada: 1995); Abraham T. Girgih, He

Rong and Sunday A. Malomo et al., “Structural and Functional Characterization of Hemp Seed (*Cannabis sativa* L.) Protein-derived Antioxidant and Antihypertensive Peptides”, *Journal of Functional Foods* (2014), 6, pp. 384-394; Shweta Khandelwal, Laura Kella and Richa Malik et al., “Impact of Omega-6 Fatty Acids on Cardiovascular Outcomes: A Review”, *Journal of Preventive Cardiology* (2013), 2(3), pp. 325-336; James D. House, Jason Neufeld and Gero Leson, “Evaluating the Quality of Protein from Hemp Seed (*Cannabis sativa* L.) Products through the Use of the Protein Digestibility-corrected Amino Acid Score Method”, *Journal of Agricultural and Food Chemistry* (2010), 58(22), pp. 11801-11807.

chic activity. Frequent and extensive European users have described the use of hemp foods and cosmetics as safe, without adverse health effects or positive urine tests for cannabis (marijuana) consumption.²⁴

Therefore, in recent years there has been a substantial increase in hemp production for food destination. Within a rapidly developing sector,²⁵ the tendency seems to be for “zero kilometre” food with distinct technological and economic values.²⁶

However, there is an actual need to implement current EU official analytical methods such as Regulations (EEC) No 1164/89²⁷, (EC) No 2860/2000²⁸, and (EC) No 796/2004²⁹ for the analysis of *Cannabis sativa L.* plants and derived products, in order to differentiate between the psychoactive compound THC and other non-psychoactive plant components.³⁰ Moreover, plant components survey both on genetic and absolute/relative cannabinoid composition in

the breeding material³¹ is one of the key aspects to be considered to develop desiderates and controlled accessions.

Synthetic compounds (i.e. synthetic cannabinoid receptor agonists, new psychoactive substances) represent an actual issue regarding the adulteration of herbal products obtained from *Cannabis sativa L.*³² Nonetheless, the identification of both natural-occurring³³ and adulterants via high throughput analytical methodologies³⁴ in cannabis and “spices” or “legal highs”³⁵, should be able to give more insight to avoid health-related concerns.³⁶

The United Nations Office on Drugs and Crime (UNODC) and drugs working groups of the European Network of Forensic Science Institutes (ENFSI) have also proposed modern analytical techniques and sampling manuals³⁷ to overcome these difficulties.

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- 24 Dirk W. Lachenmeier, “Hanfhaltige Lebensmittel – ein Problem?“, *Deutsche Lebensmittel Rundschau* (2004), 100(12), pp. 481-490; Valerie L. Vantreese, “Hemp Support: Evolution in EU Regulation“, *Journal of Industrial Hemp* (2002), 7(2), pp. 17-31.
- 25 Helga Mölleken, “Hanf (*Cannabis sativa*) als Novel Food“, *BlOforum–Forschung und Entwicklung* (1999), 22, pp. 452-457; Sergio Montserrat-de la Paz, Fabiola Marín-Aguilar and María Dolores García-Gimenez et al., “Hemp (*Cannabis sativa L.*) Seed Oil: Analytical and Phytochemical Characterization of the Un-saponifiable Fraction“, *Journal of Agricultural and Food Chemistry* (2014), 62(5), pp. 1105-1110.
- 26 Olga Radočaj, Etelca, Dimić and Rong Tsao, “Effects of Hemp (*Cannabis sativa L.*) Seed Oil Press-Cake and Decaffeinated Green Tea Leaves (*Camellia sinensis*) on Functional Characteristics of Gluten-Free Crackers“, *Journal of Food Science* (2014), 79(3), pp. C318-C325.
- 27 Commission Regulation (EEC) No 1164/89 of 28 April 1989, laying down detailed rules concerning aid for fibre flax and hemp, OJ L 121, 29.4.1989, p. 4-10.
- 28 Commission Regulation (EC) No 2860/2000 amending Regulation (EC) No 2316/1999 laying down detailed rules for the application of Council Regulation (EC) No 1251/1999 establishing a support system for producers of certain arable crops, to include flax and hemp grown for fibre, specifying the rules on set-aside areas and amending the base areas for Greece and Portugal, OJ L 332, 28.12.2000, p. 63-75.
- 29 Commission Regulation (EC) No 796/2004 of 21 April 2004 laying down detailed rules for the implementation of cross-compliance, modulation and the integrated administration and control system provided for in Council Regulation (EC) No 1782/2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers, OJ L 141, 30.4.2004, p. 18-58.
- 30 J.C. Callaway, “A More Reliable Evaluation of Hemp THC Levels Is Necessary and Possible“, *Journal of Industrial Hemp*, (2008), 13(2), pp. 117-144; EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), “Scientific Opinion on the Risks for Human Health Related to the Presence of Tetrahydrocannabinol (THC) in Milk and Other Food of Animal Origin“, *EFSA Journal* (2015), 13(6):4141, p. 125.
- 31 Daniela Pacifico, Francesca Miselli and Mirta Micheler et al., “Genetics and Marker-assisted Selection of the Chemotype in *Cannabis sativa L.*“, *Molecular Breeding* (2006), 17(3), pp. 257-268.
- 32 Simon Hudson and John Ramsey, “The Emergence and Analysis of Synthetic Cannabinoids“, *Drug Testing and Analysis* (2011), 3(7-8), pp. 466-478; Susana S. Simões, Inês Silva and Antonio Castanera et al., “Validation and Application of an UPLC–MS/MS Method for the Quantification of Synthetic Cannabinoids in Urine Samples and Analysis of Seized Materials from the Portuguese Market“, *Forensic Science International* (2014), 243, pp. 117-125.
- 33 Nerea Ferreirós, “Recent Advances in LC-MS/MS Analysis of Δ^9 -tetrahydrocannabinol and Its Metabolites in Biological Matrices“, *Bioanalysis* (2013), 5(21), pp. 2713-2731.
- 34 Marisol S. Castaneto, Ariane Wohlfarth and Nathalie A. Desrosiers et al., “Synthetic Cannabinoids Pharmacokinetics and Detection Methods in Biological Matrices“, *Drug Metabolism Reviews* (2015), 0, pp. 1-51; Filomena Lelario, Laura Scranò and Luigi Milella et al., “Cannabinoid Profile and Chemotype of Hemp Plants by Using LC-FTICR MS and Tandem Mass Spectrometry Performed by IRMPD and CID“, *Massa* (2015), June 2015.
- 35 Lebel P. et al., “Rapid Determination of 24 Synthetic and Natural Cannabinoids for LC–MS–MS Screening in Natural Products and Drug Inspection Applications“, *Spectroscopy* (2015), Issue 1.
- 36 William D. Hoffmann and Glan P. Jackson, “Forensics“, *Annual Review of Analytical Chemistry* (2015), 8(1); Paul Posadzki, Leala K. Watson and Edzard Ernst, “Contamination and Adulteration of Herbal Medicinal Products (HMPs): an Overview of Systematic Reviews“, *European Journal of Clinical Pharmacology* (2013), 69(3), pp. 295-307; Justice Tetley and Conor Crean, “New Psychoactive Substances: Catalysing a Shift in Forensic Science Practice?“, *Philosophical Transactions of the Royal Society B* (2015), 370(1674), 20140265.
- 37 United Nations Office on Drugs and Crime (UNODC), “Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products“, *UN document* (2009), ID: ST/NAR/40; United Nations Office on Drugs and Crime (UNODC), “Recommended Methods for the Identification and Analysis of Synthetic Cannabinoid Receptor Agonists in Seized Materials“, *UN Document* (2013), ID: ST/NAR/48; Drugs Working Group of the European Network of Forensic Science Institutes (ENFSI) and UNODC, “Guidelines for Representative Drug Sampling“ (2009).

II. The Italian Case and the Need for a Harmonised Legal Framework for Hemp Foods

The production of hemp food goods in Italy is low and irregular. Therefore, primary producers and traders require clear, simple and logic regulations.

From a regulatory perspective, there is no barrier to the use of *Cannabis sativa L.* in food production, and there are not specific THC limits established at EU level.

In Italy, the main obstacles are attributable to the drug regulatory framework, which is very strict and forbids any kind of incitement to the use of drugs through advertising (art. 82, D.P.R. 309/1990). Therefore, food producers should refrain from developing and running advertisement campaigns based on leaves and/or containing “hippie” symbols so as to avoid the infliction of administrative sanctions up to € 25,000.

Moreover, art. 26 D.P.R. 309/1990, in line with art. 39 of Regulation (EC) No 73/2009³⁸ and whereas (51) of Regulation (EC) No 1122/2009³⁹, provides that only hemp-type accessions with a THC content not exceeding 0.2 % can be cultivated for industrial purposes. This provision requires producers to be extremely prudent when buying seeds or plant parts from non-EU suppliers, because the use of unauthorized or unregistered cultivars could expose them to criminal liability pursuant to D.P.R. 309/1990.

The other argument raised against the use of *Cannabis sativa L.* seeds in food production is based on the assumption that THC has to be considered a contaminant and, therefore, a zero tolerance approach to its accidental contamination in food should be applied.

Such an interpretation, which some competent authorities initially embraced at the local level, caused a delay in the production and marketing of such food-stuffs in Italy. Today, following the developments outlined in this article, the situation is completely changed, and it is quite common to find on the market bread, pasta and cereal products (but also ice cream, oil and other product categories) made with or containing *Cannabis Sativa L.* seeds.

Indeed, the argument raised was not consistent with the contaminants regulatory framework at EU level. Namely, art. 2 of Regulation (EEC) No 315/93⁴⁰ provides that:

1. Food containing a contaminant in an *amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market.*
2. Furthermore, *contaminant levels shall be kept as low as can reasonably be achieved by following good practices* at all the stages referred to in Article 1.
3. In order to protect public health and pursuant to paragraph 1, the Commission may where necessary establish the maximum tolerances for specific contaminants.”(e.g. Regulation (EC) No 1881/2006⁴¹).

From what precedes, it is clear that only the most frequent and dangerous contaminants (i.e. heavy metals in fishery products) are considered in specific measures as Regulation (EC) No 1881/2006.

Where no limit is set at EU level, the general rule is that the amount of contaminants detectable has to be safe from a toxicological perspective and unavoidable despite the application of good manufacturing practices. This is precisely the THC case: due to low levels of THC in the permitted cultivars and careful checks during the plant production, the THC residues are usually not significant as a public health threat.

The Italian Ministry of Health aligned with this approach by means of a circular sent to local competent authorities and trade associations in 2009 (No 15314 issued on 22 May 2009), although discussions are still ongoing.

In the circular, the Ministry outlined that under these circumstances the general principles on food

38 Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003, OJ L 30, 31.1.2009, pp. 16-99.

39 Commission Regulation (EC) No 1122/2009 of 30 November 2009, laying down detailed rules for the implementation of Council Regulation (EC) No 73/2009 as regards cross-compliance, modulation and the integrated administration and control system, under the direct support schemes for farmers provided for that Regulation, as well as for the implementation of Council Regulation (EC) No 1234/2007 as regards cross-compliance under the support scheme provided for the wine sector, OJ L 316, 2.12.2009.

40 Council Regulation (EEC) No 315/93 of 8 February 1993, laying down Community procedures for contaminants in food, OJ L 37, 13.2.1993, pp. 1-3.

41 Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in food-stuffs, OJ L 364, 20.12.2006, pp. 5-24.

safety must be applied, namely Regulations (EC) No 178/2002⁴² and (EC) No 852/2004⁴³. Moreover, the Italian Superior Institute of Health (ISS) established the genetic absence of THC in seeds and recommended to use limits provided by other countries as a benchmark (today only three European countries established specific limits: Belgium, Germany and Switzerland).

42 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, pp. 1-24.

43 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 135, 23.5.2002, pp. 17–19 (emphasis added).

44 Rudolf Brenneisen et al., "Scientifically Sound Guidelines for THC in Food in Europe", *European Industrial Hemp Association (EIHA)* (2015).

Taking as a reference the EFSA database on consumption habits of EU consumers as well as data provided by the Food Standards Australia New Zealand (FSANZ) and the German Bundesinstitut für Risikobewertung (BfR); the ISS in a note (No 44595 issued on 15 July 2008) considered safe a dose of **1.5 mg/kg bodyweight/day**. ISS also suggested some limits for the unintentional contamination in relation to certain categories of foodstuffs, notably:

- *Cereals and products thereof (including pasta and bakery)*: **2.4 mg/kg** product;

- *Beverages*: **0.063 mg/kg** product; and

- *Oil*: **4.43 mg/kg** product.

In light of the outlined uncertainties, on 26 October 2015, the European Industrial Hemp Association (EIHA) proposed scientifically-driven guidelines at EU level for THC in hemp foods,⁴⁴ but at the moment the issue remains open.