

The phyto-therapeutic oil par excellence? It is not yet in Farmacopea

For extra virgin olive oils there is a gap between food quality and medical quality. Tullia Gallina Toschi thinks this gap should be filled as soon as possible, by referring to the updated European norm for quality and genuineness criteria

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The extra virgin olive oil birthday was celebrated in Italy last December 2nd, 2010. The quality definition was formally expressed in the Law 13 November 1960, n. 1407, G. U. n. 295 del 2 December 1960):

”Extra virgin olive oil”, (denomination) reserved to oil which, after being mechanically obtained from olives, has not received any chemical manipulation, but only washing, sedimentation, filtration, with lower than 1% degree of acidity, express as oleic acid, without any tolerance; to the denomination “extra virgin olive oil” the origin can be added.

This article introduced the concept of superior quality, obtainable only by improving the pressing procedures, the preservation of olives and of oil. This category cannot be modified, according to the law.

In later laws and rules, it was further strengthened the idea that an extra virgin olive oil cannot undergo chemical and biochemical processes. It is therefore defined as a “phyto-therapeutic” product, rich in phenols, and unsaponifiable components, with absolute limitations of extraction techniques to physical processes (press, centrifugation, filtration). It is basically the fatty phase of an olive crush.

After fifty years, the Reg. CE 1513/01 of November 1st 2003 also diminished the acidity from 1% to 0.8%. It is now possible to enforce stricter conditions on the “superiority” of extra virgin oils, so that the international quality (COI and EU), as a basic analytical method, increases, by a 20% reduction of the limiti.

From 1960 until 1991 the development and approval of analytical method for the certification of purity and genuineness, and the revolution brought by the sensorial analysis, define a product which has seen the most norms about it in the world, in the food field.

A legitimate question is how olive oil is defined and its quality described when it is mentioned as a medication, according to the specifics of the “Official Pharmacopeia” (OP).

Some vegetal products, together with several other categories (pure substances extracted or synthesized) are defined in monographs where their quality requirements are described, in the Pharmacopeia of each country and in the UE one too.

In the past Pharmacopeias olive oil was included since long ago. In 1940 (OP VI) “1’Oleum Olivarum” was defined as a refined product, a clear liquid, slightly yellow-greenish or straw-yellow in color, with a weak smell and characteristic flavor. A quality criterion was already being “organoleptic”, when the law says that oil should not have “any rancid [smell or taste], or any unpleasant smell, not even after heating in water.”

Acidity as a quality requirement is expressed in oleic acid and should not be higher than 2 %. Among preparations, camphorated oils (rhinologic preparations or massage oil), poultices and chamomile oils are listed. Olive oil is utilized in these preparations as a vehicle for lipid active principles and as a fatty, albeit liquid, phase, at room temperature, of poultices and liniments.

This law which dates back to 1940 already specified olive oil requirements for injectable preparations. In the FU VIII (1965) it is specified that oil for parenteral use must be absolutely neutral. This law was published five years after Law n. 1407, November 13th 1960, that is when extra virgin olive oil was defined by law, but FU VIII did not cite any mechanical process or the virginity of the product, as it still referred to a refined oil.

From the standpoint of medicament development, ignoring the “superior extractive quality” was understandable, considering that phyto-therapeutic and herbalist products gained popularity in the ‘80s. In 1985, the Italian Health Ministry published FU IX, in which olive oil was for the first time defined as “[a product] obtained by cold pressing, or other adequate mechanical processes, from the ripe drupe of *Olea Europea L*”. The non refined oil was thus admitted to Pharmacopeia, but not yet the extra virgin.

The acidity limit was 2%, that is the limit of virgin oils. In FU X (1989), the monograph maintains a 2% acidity limit and 0.5% for injectability. It is still a definition which lies halfway between the virgin oil, the refined oil and the oil obtained through cold pressing. This makes unclear the limits of a univocal pharmaceutical quality.

The European law (VII edition, January 1st 2011) does not make things much clearer, as it includes two different monographs for refined olive oil (0.3% acidity) and virgin oil (2% acidity). A superior quality is not mentioned, although it should be preferred especially when a product is used as a medicament. European Pharmacopeia too does not seem very much updated as far as analytical determinations useful to define quality. For instance, the identification of fatty acids is still proposed through thin layer chromatography, while gas chromatography has been used for more than twenty years.

A gap between food and medical quality is apparent, and European Pharmacopeia should take care of this issue, at least by referring to European laws on quality and genuineness (CEE n. 2568/91), which have been recently updated (UE n. 61/2011) by including innovative methods for the assessment of alcohol-esters to unmask the deodorized frauds, and by citing the methods and limits to define the quality of extra virgin oils.

One last note of bitterness. The Health Minister includes several oils, such as VINACCIOLI and ENOTERA oils, among substances which can be used for the extemporaneous preparation of healthy products by chemists (galenic formulations). The parts of *Olea Europea L*. which can be used are: fruits, leaves, sprouts, and buds. The extra virgin oils obtained from drupe may be considered included as an understatement, but is it too much to expect the legislator to expressly report the healthier Mediterranean oil, the most cited by the scientific literature worldwide as one of the main substances and vegetal formulation for healthy purposes, in the next revision of the law?

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