

General considerations on pesticide residues in olive oils

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RISG
Anniversario
100

Presentato al centenario RISG

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ricerca, innovazione
e scenari futuri**

15 novembre 2023

The olive tree is one of the most important and ancient crops in the Mediterranean area where, according to the latest data from the International Olive Council, 92% of the world's olive oil is produced. The olive tree can be attacked by a large variety of parasites, resulting in a reduction in the quality and quantity of olives and olive oil produced.

Most of the plant protection products used on olive trees are insecticides, acaricides and fungicides and also herbicides considering that olives can also be harvested with the beating technique from tents placed on the ground. The traces of plant protection products that can be found in olives are named "residues".

The Maximum Residue Level (MRL) is defined as the highest level of a pesticide residue that is legally tolerated in or on a food or feed when plant protection products are applied according to Good Agricultural Practice (GAP).

The MRL values of pesticide residues in olives (as for all crops) are defined in Regulation (EC) 396/2005 and subsequent updates for all possible food-pesticide combinations and can be consulted in a European Commission database.

To calculate MRLs in olive oil, process factors must be applied to the MRL values on olives. In the European Union coordinated multi-annual control programmes, each Member State is required to report the process factors used to analyze olive oil samples. The SANTE 10704/2021 document represents an information document from the European Commission for the application of process factors which are however set by the National Authorities. Currently in Italy the process factor for olive oil is equal to 5.

1. INTRODUCTION

Pesticides or plant protection products (PPP) are compounds belonging to different chemical classes, used in agriculture, livestock farming, public hygiene, domestic life and industrial products to control many harmful or unwanted organisms, plant or animal. They are divided according to their field of action into different categories as example: insecticides/acaricides, herbicides, fungicides, phyto regulators.

Depending on their chemical structure and associated chemical-physical properties and the type of use and method of application, not all of the applied dose is degraded and small quantities of original pesticides can persist in foods, animals and the environment as explained in Figure 1.

The olive tree is one of the most important and ancient crops in the Mediterranean area where, according to the latest data from the International Olive Council, 92% of the world's olive oil is produced

Olive oil is one of the main components of the Mediterranean diet and also an export product with a high economic impact.

The olive tree can be attacked by numerous parasites, also as a result of climate changes and consequent increase in average temperatures leading in a reduction in the quality and quantity of olives and olive oil produced. Most of the PPP used on olive trees are insecticides, acaricides and fungicides and also herbicides considering that olives can also be harvested with the beating technique from tents placed on the ground.

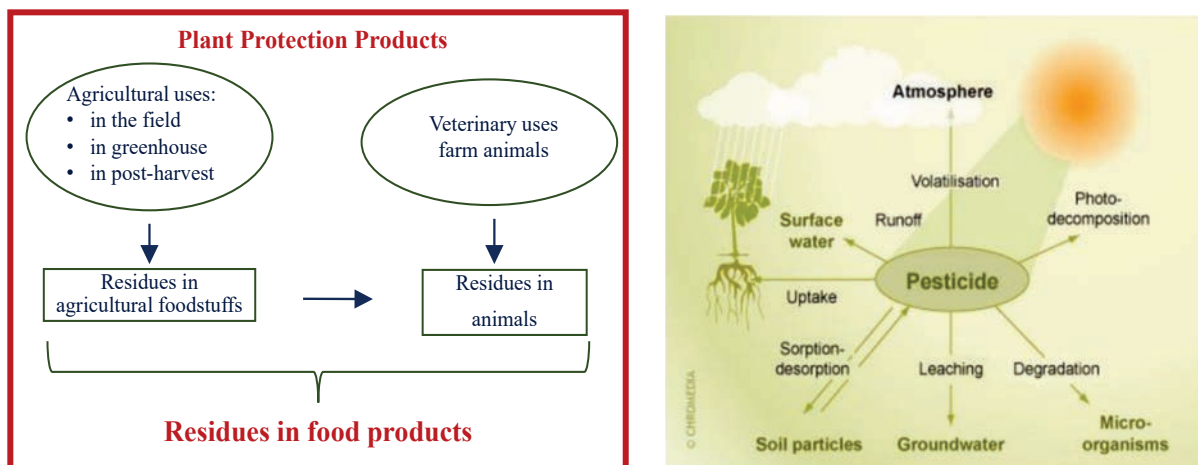


Figure 1 – Scheme of possible presence of pesticide residues in food products and in the environment

The official control on residues of phytosanitary products in olives, olive oil and in all foods falls within the controls provided for by European Commission (EC) Regulation 2017/625 [1] and within the scope of EC Regulation 396/2005 [2] and represents one of the most relevant health priorities in the field of food safety, with the aim of guaranteeing a high level of consumer protection.

Regulation (EC) 396/2005 [2] indicates the procedure for setting the Maximum Residue Level (MRL) for each pesticide in or on food products and feed of plant and animal origin.

MRL means the maximum allowable quantity of active ingredient residue present in agricultural commodities, after treatments with PPP which does not pose risks to the health of the consumer and it is expressed in mg/kg.

The structure of Regulation (EC) 396/2005 [2] is described in Table I.

Table I – Structure of Regulation (EC) 396/2005

Regulation (EC) 396/2005	
50 articles governing procedures required for fixing or deleting MRL and their provisions for official controls at National and Community level	
ANNEX I	list of products to which the regulation is applied, last update Regulation (EU) 2018/62
ANNEX II	list of MRLs for each active substance/product combination included in annex I, continuous updating
ANNEX III	list of provisional MRL
ANNEX IV	list of active substances for which it is not necessary to fix MRL
ANNEX V	list of MRLs not present in Annexes II and III or for active substances not listed in Annex IV
ANNEX VI	list of processing factors not yet published
ANNEX VII	list the combinations of active substance/product subject to derogation as regards post-harvest treatment with a fumigant

The setting of MRL is a complex process harmonized by EFSA which takes into account good agricultural practices (GAP), conditions of use, doses, number of treatments, safety intervals which are determined by residual field studies. These residue levels are assessed both during the authorization phase of active substances, during the authorization phase of PPP and in the event of a non-compliant product being found on the market. This assessment is carried out by comparing consumer exposure estimates with toxicological parameters such as acute reference doses (ARfD) (for acute risk assessment) and acceptable daily doses (ADI) (for chronic risk assessment).

The MRL are not considered as toxicological limits, so exceeding them does not pose a danger to humans, but rather constitute the maximum quantity of residue that could be present on a product of plant origin when GAP are respected during use of PPP.

The established limits MRL are uniformly applied throughout Europe and are continuously updated. All crop/pesticide combinations can be consulted using a specific database on the EC website.

The official control on residues of PPP in foods falls within the controls provided for by EC Regulation 2017/625 [1] and within the scope of EC Regulation 396/2005 [2] mentioned above.

The EC issues coordinated three-year control programs to ensure compliance with maximum levels of pesticide residues and to assess consumer exposure to pesticide residues in and on food products of plant and animal origin.

These regulations establish the pesticide/food product combinations that each member state must monitor as well as the minimum number of samples to be analyzed, considering processed food products such as olive oil among the samples to be analyzed. The scheme of the last control program is Regulation (EU) 2023/731 [3] is shown in Figure 2 where it is highlighted that in the year 2024 one of food products subjected to official control is olive oil. Member States are required to communicate the processing factors (Pf) used in the case of analysis of olive oil as all processed products considered.

L 95/28 EN Official Journal of the European Union 4.4.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/731
of 3 April 2023

concerning a coordinated multiannual control programme of the Union for 2024, 2025 and 2026 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin and repealing Implementing Regulation (EU) 2022/741

ANNEX I
PART A
Products (*) of plant origin (†) to be sampled in 2024, 2025 and 2026

2024 (b)	2025 (c)	2026 (a)
(0151010) Table grapes (*)	(0130010) Apples (*)	(0110020) Oranges (*)
(0163020) Bananas (*)	(0152000) Strawberries (*)	(0130020) Pears (*)
(0110010) Grapefruits (*)	(0140030) Peaches, including nectarines and similar hybrids (*)	(0162010) Kiwi fruits (*)
(0231030) Aubergines (*)	Wine (red or white) made from (0151020) Wine grapes (where no specific processing factors for wine are available, Member States shall report the wine processing factors used).	(0241020) Cauliflowers (*)
(0241010) Broccoli (*)	(0251020) Lettuces (*)	(0220020) Onions (*)
(0233010) Melons (*)	(0242020) Head cabbages (*)	(0213020) Carrots (*)
(0280010) Cultivated fungi (*)	(0231010) Tomatoes (*)	(0211000) Potatoes (*)
(0231020) Sweet peppers/bell peppers (*)	(0252010) Spinaches (*)	(0300010) Beans (dried) (*)
(0500070) Wheat grain (*)	(0500050) Oat grain (*), (*)	(0500070) Rye grain (*)
Virgin olive oil from (0402010) Olives for oil production (where no specific oil processing factor is available, Member States shall report the processing factors used).	(0500010) Barley grain (*), (*)	(0500060) Brown rice (husked rice), defined as rice after the removal of the hull from paddy rice (*)

(*) Only processed products shall be analysed. In case of products sampled in frozen state, a processing factor shall be reported, if applicable.
 (†) If no sufficient samples of rye, wheat, oat or barley grains are available, also rye, wheat, oat or barley whole grain flour can be analysed and a processing factor shall be reported.
 (*) If no sufficient samples of oat grains are available, the part of the required sample number for oat grains that could not be taken, can be added to the sample number for barley grains, resulting in a reduced sample number for oat grains and a proportionately increased sample number for barley grains.
 (†) If no sufficient samples of barley grains are available, the part of the required sample number for barley grains that could not be taken, can be added to the sample number for oat grains, resulting in a reduced sample number for barley grains and a proportionately increased sample number for oat grains.
 (†) Where appropriate, also polished rice grain can be analysed. It shall be reported whether polished or husked rice was analysed. If polished rice was analysed, a processing factor shall be reported.

Figure 2 – Scheme of Regulation (EU) 2023/731

2. PROCESSING FACTORS (Pf)

The Regulation (EC) 396/2005 [2] established MRL values for primary food matrices only. In order to establish the maximum acceptable residue in and on the relevant processed products, the article 20 of this Regulation states: "For processed food and feed products and/or composites for which MRLs have not been fixed, those laid down for the relevant product referred to in Annex I shall apply, taking into account changes in the residue content resulting from the processing and/or to mixing. Specific concentration or dilution factors for certain processing operations and/or mixtures or for certain processed and/or composite products may be included in the list set out in annex VI"

As mentioned above the Pf list (Annex VI) have not yet been defined by the EC.

The EC published the SANTE 10704/2021 document [4] entitled: *Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors, processed and composite food and feed*.

The purpose of this document is not to establish factors of harmonized processing at EU level, but provide one tool for Member States on how to implement the provisions of Article 20 of Reg. 396/2005 in a harmonized way, so that the processing factors established by a Member State may be mutually accepted by the other Member States. In the Figure 3 is shown the definition of processing factor as presented in the SANTE document.

$$Pf = \frac{\text{Residue in the processed fraction (mg/kg)}}{\text{Residue in the raw commodity (mg/kg)}}$$

Pf is > 1: Residues concentrated in the processed product.

Pf is < 1: Residues declined in the processed product (due to dilution, removal or degradation).

Pf = 1: Processing did not result in a change of residue concentrations.

Figure 3 – Definition of processing factor according to the SANTE 10704/2021 document

SANTE document defined two different kinds of Pf: substance-specific processing factors and generic processing factors for certain standard processing operations (e.g., drying by removing of water). Generic processing factors should only be used when substance specific factors are not available Available sources of specific processing factors are listed below:

- *EFSA publications and EFSA (EU) database* The EFSA (EU) database includes processing factors from EFSA publications until June 2016. Work is currently ongoing to implement additional processing information from more recent EFSA publications
- *National databases in the European Union*. The German Federal Institute for Risk Assessment (BfR), the Dutch National Institute for Public Health and the Environment (RIVM), the Spanish Agency for Food Safety and Nutrition (AESAN)
- *Joint Meeting on Pesticide Residues (JMPR) reports*. The residue definitions for enforcement derived by JMPR should match with the EU residue definitions for enforcement
- *Other sources* (e.g., Souci-Fachmann-Kraut database (SFK) for food composition, the database from the European Spice Association (ESA), the dataset of the Association of Organic Processors etc.)

When multiple Pf are available it should be taken the most appropriate for the specific situation considering that there is no hierarchy between the national databases of the Member States.

If several Pf are available, it would be recommended to use the median processing factors from the EFSA process (EU) or national databases.

When specific substance processing factors are not available it is possible used generic processing factors as in the case of olive oil explained in the SANTE document and showed in the Figure 4.

Example: the yield factor between olive oil (processed commodity) and olives (unprocessed product) is considered to be 20%. If no other processing factors are available, this factor could be considered, but only if information on the physico-chemical properties of the residues, in particular their fat/water solubility (via log Kow, also known as logP), is also taken into account.

Assuming that residues fully concentrate into the processed commodity of olive oil, the processing factor is derived according to the following equation:

$$Pf = \frac{1}{\text{yield factor}} = \frac{\text{mass olives}}{\text{mass olive oil}} = \frac{100}{20} = 5$$

The derived MRL of the olive oil (processed commodity) can be calculated by multiplication of the MRL of olives (unprocessed product) by the processing factor of 5.

Figure 4 – Generic processing factor of olive oil according to the SANTE 10704/2021 document

According to the SANTE document the Pf are applied:

- approved and non-approved active substances in the EU
- refer to the residue definition for enforcement laid down in Regulation (EC) No 396/2005
- MRLs established at a specific LOQ or at the default level of 0.01 mg/kg

The SANTE/10704/2021 [4] document has been conceived as an information note of the Commission Services and it does not represent the official position of the Commission. It does not intend to produce legally binding effects. However, it remains ultimately the Member States responsibility to decide, after analysis of available information, on whether to use or not to use processing factors and, if used, to decide on an appropriate factor as a basis for taking enforcement action

Regarding the Pf for olive oil, many countries member of European Community or however many olive oil producers of Mediterranean area, used a Pf of 5 as in Italy where this Pf is established by an Official Circular of Health Minister dated 17th November 2015.

3. OFFICIAL CONTROLS

As mentioned previously the official control on residues of PPP in foods falls within the controls provided for by EC Regulation 2017/625 [1] and within the scope of EC Regulation 396/2005 [2].

The Ministry of Health coordinates and defines official control programs on food products in Italy, also including annual plans regarding residues of PPP in foods. Part of the controls carried out at national level are an integral part of the coordinated official control programs envisaged by the European Union.

The controls are carried out on both internally produced and imported foods to ascertain the respect of the MRL of pesticides in foods on the national territory.

Furthermore, to improve the uniformity and reliability of European controls in the field of pesticide residues in food, the EC establishes, pursuant to Article 93 of EC Regulation 2017/625 [1], four European Reference Laboratories (EURL) that deal with residues of pesticides in various sectors:

- Cereals and feed
- Food products of animal origin and foods with a high fat content
- Fruits and vegetables, including foods with high water and acid content
- Single residues methods

The main task of these Reference Laboratories is to ensure the quality and comparability of the data provided by the various European countries on pesticide residues in food.

Member state also designate, according to Article 100 of the EC Regulation 2017/625 [1], one or more National Reference Laboratories (NRL) for each EURL.

In Italy, four NRL have been designated for residues of PPP in foods: three of these are at the Istituto Superiore di Sanità:

- National Reference Laboratory for Fruit and Vegetables
- National Reference Laboratory for Food of Animal Origin and foods with a high fat content
- National Reference Laboratory Single Residues Methods

one laboratory at the Istituto Zooprofilattico Sperimentale (IZS) del Piemonte e Valle D'Aosta:

- National Reference Laboratory for Cereals and Feeding Stuff

Official control are carried out by the official control laboratories (A.R.P.A., AASSLL and IZS) identified by the Regional Health Departments. These laboratories must be accredited as required by EC Regulation 2017/625 [1], according to the UNI ISO/17025 standard [5], with analysis methods validation according to a European guide document SANTE/11312/2021 [6]: *Analytica Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed*, updated every two years. They must also participate in the Proficiency Test (PT) organized by the EURL and by NRL as required by Regulation 396/2005 [2].

The Istituto Superiore di Sanità in its role of NRL annually organize a PT for the determination of pesticide residues in olive oil in which European NRL, European official control and private laboratories participate.

Results of the Italian Control Plans for pesticide residues in food are summarized in a final report published by the Ministry of Health and the last one published concerns the monitoring data for the year 2020 [7].

Considering the olive oil, 214 samples were analysed. The percentage of samples without detectable residues was found to be 93.5% and no samples showed residues exceeding the legal limit. The data regarding the olive oil matrix certainly shows a situation of absence of risk for the consumer.

Overall, as in the past few years, the results of official Italian controls continue to be in line with those found in other EU countries and indicate a high level of consumer protection.

4. REFERENCES

- 1] Europe. Regulation (EU) 2017/625 of the European Parliament and the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. *Official Journal of the European Union* L95/1, 7 April 2017.
- 2] Europe. Regulation (EC) NO 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. *Official Journal of the European Union* L70/1, 16 March 2005.
- 3] Commission Implementing Regulation (EU) 2023/731 of 3 April 2023 concerning a coordinated multiannual control programme of the Union for 2024, 2025 and 2026 to ensure compliance with maximum residues levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin and repealing Implementing Regulation (EU) 2022/741. *Official Journal of the European Union* L95/28, 4 April 2023.
- 4] European Commission – Directorate-General for Health and Food Safety. Note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors, processed and composite food and feed. Brussels: European Commission (SANTE/10704/2021).
- 5] ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories. Geneva: International Organization for Standardization; 2005. Upgraded 2018.
- 6] SANTE/11312/2021) document "*Analytica Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed*" Supersedes Document No SANTE/2019/12682. Implementing by 01/01/2022.
- 7] Ministero della Salute, Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e la Nutrizione. Relazione sul controllo ufficiale sui residui di prodotti fitosanitari negli alimenti - Dati anno 2020. (https://www.salute.gov.it/imgs/C_17_pubblicazioni_3284_allegato.pdf)