

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



Prospects for better regulation of food safety

Technical guidance on cork

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DGAV

National Veterinary and Phytosanitary Authority,

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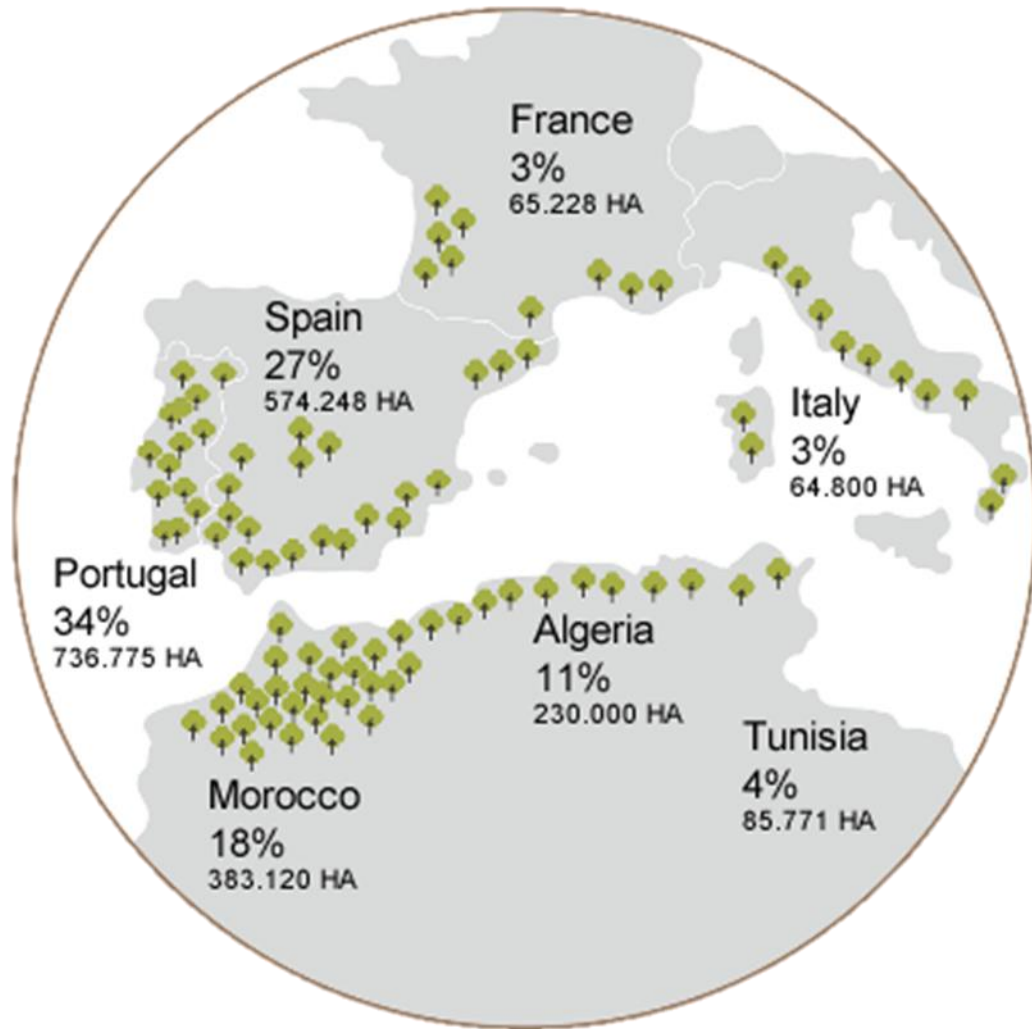
Responsible Authority for the Management of the Food Safety System

MISSION

Definition, coordination of application and assessment of the policies of:

- food safety
- health and animal welfare
- plant health

CORK and CORK PRODUCTS



* Source: Portugal: IFN, 2019; Spain: MARM, 2012; Italy: FAO, 2005; France: IM Liege, 2014; Morocco: HCEF Maroc, 2011; Algeria: EFI, 2009; Tunisia: Ben Jamaa, 2011.

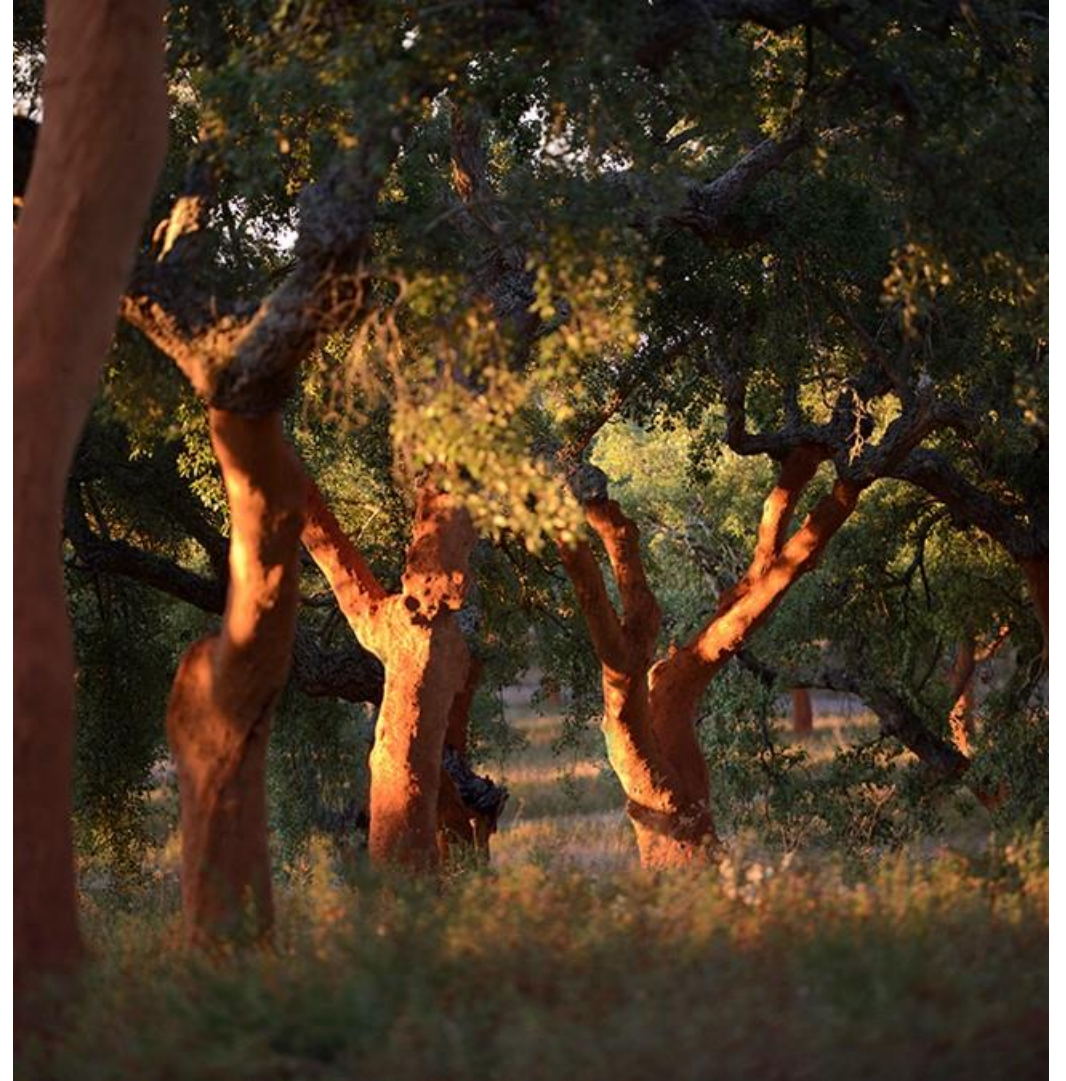
- Cork oaks occurs predominantly in the southern Portugal and Spain in a multi-propose agroforestry system, named *Montado* in Portugal and *Dehesa* in Spain.
- Cork oak can also be found in Morocco, in Northern Algeria, in Tunisia, in the south of France and on the west coast of Italy, including Sicily, Corsica and Sardinia.
- Presently, the cork oak occupies a total area of approx. 2,1 million hectares: 1,44 million hectares in Europe and 0,7 million hectares in Northern Africa.
- The Iberian Peninsula represents 61% of the cork oak forests worldwide .

Cork definition

- Cork is a natural product originating from the renewable bark of the Cork Oak.

Definition ISO 633:2019 – Cork Vocabulary

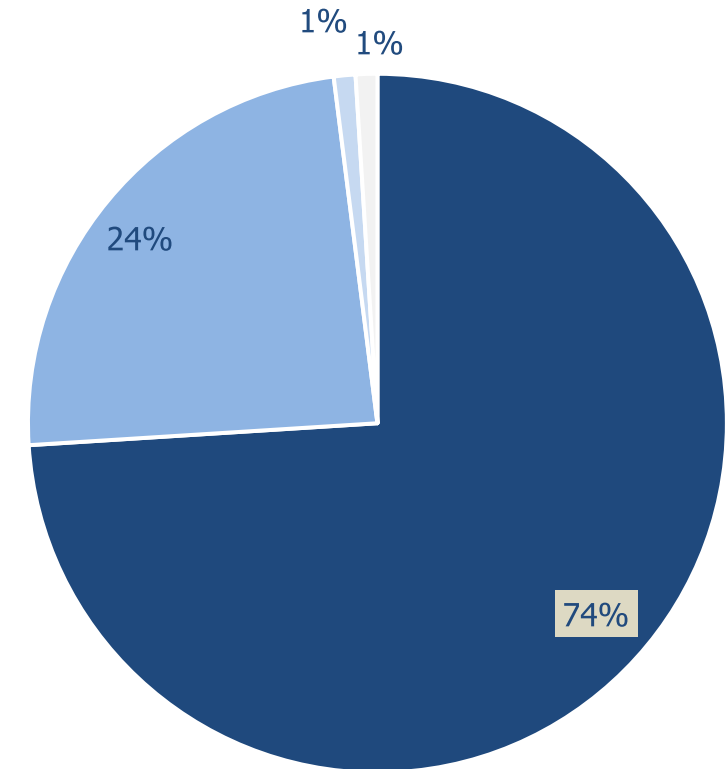
- *protective layer of bark which, periodically, can be harvested from the trunk and branches of the cork oak (Quercus suber L.) constituting the raw material for cork products*



World trade by cork product typology



Photos: copyright APCOR



- Cork stoppers
- Construction
- Others
- Natural cork

Adapted from Relatório anual de caracterização da situação económico-financeira das empresas do setor da cortiça, APCOR CORK 2022

Technical Guide on Cork

- Cork materials and articles intended to come into contact with foodstuffs



Photos: copyright APCOR

Timeline

2016

Last version of
the document
PA/PH/EMB
(11) 12 R3

Jun2023

1st draft
presentation

Sept 2024

Comments and
final remarks

Jan 2022
Portugal is
indicated
rapporteur

Jun 2024
2nd draft
presentation

4QT 2024 -
Technical
Guidance on
cork FCM

Scope

The Technical Guide applies to cork materials and articles which, in the finished state, are intended to come into contact with foodstuffs:

- Cork stoppers for sealing the container they are applied to - usually a bottle.
- Cork materials and articles' - other food contact applications made of cork include, but are not limited to, trays, placemats and fruit bowls.
- In the case of a multi-layer material or article, the layer or layers made of cork shall comply with the provisions of the Technical Guide, unless separated from the foodstuff by a functional barrier.



Photos: copyright APCOR

Scope

The Technical Guide does not apply:

- Cork stoppers may have a capsule (bar top) made of a different material such as plastic, wood, glass or metal (These materials are excluded from the scope of this Technical Guide).
- Materials other than cork, such as organic or inorganic coatings, paraffinic waxes or silicones, which are present in the form of a layer or layers on the surface of the cork materials or articles.



Photos: copyright APCOR

Definitions

- Cork: protective layer of bark which, periodically, can be harvested from the trunk and branches of the cork oak (*Quercus suber* L.) constituting the raw material for cork products (ISO 633:2019).
- Cork materials: whole pieces of cork or two or more pieces of cork or granulated cork which are bound together by means of glue or adhesive. Cork materials and articles shall comply with the definitions given in ISO 633:2019.



Photos: copyright APCOR

Specific requirements

- Cork material for food contact must comply:

General requirements defined in Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food:

- Regulation (EC) No. 1935/2004
- Regulation (EC) No. 2023/2006,
- Other relevant national legislation

The List of substances used in the manufacture of cork materials and articles intended to come into contact with foodstuffs, and

shall comply with the restrictions and specifications laid down therein

Specific requirements

Under normal or foreseeable conditions of use, cork FCM shall not transfer their constituents to food in quantities which could:

- a. endanger human health; or
- b. bring about an unacceptable change in the composition of the food; or
- c. bring about a deterioration in the organoleptic characteristics thereof

Food business operators shall ensure that they use cork food contact materials and articles during food production or preparation, storage and distribution in a way that does not compromise compliance with applicable rules and recommendations.

Compliance testing

Cork

- Cork used to produce cork materials and articles may be treated with products that contain active substances to protect plants or plant products if these products have been authorised for this use in accordance with Regulation (EC) No 1107/2009 ;

Cork Materials and articles:

- Cork Materials and articles Shall comply the maximum residue levels of pesticides in food as laid down in Regulation (EC) No 396/2005;
- Cork Materials and articles shall not contain any fungi, fungal toxins or bacteria, which may present a risk to human health or cause unacceptable changes in the foodstuffs.
- Verification of compliance with the restrictions applicable to the substances stated in list (annex) shall be carried out in accordance with the test conditions defined in the Guidance

Test conditions and methods of analysis

The following documents shall be applied:

- The food simulants and compliance testing conditions set out in Regulation (EU) No 10/2011
- the guidelines set by JRC in the publication: Testing conditions for kitchenware articles in contact with foodstuffs: plastics metals, silicone & rubber, paper & board
- The determination of overall migration from cork materials and articles shall be conducted according to EN 1186:2022
- The determination of overall migration from cork stoppers shall be conducted according to ISO 10106:2021

Annex

List of evaluated substances used in the manufacture of cork materials and articles intended to come into contact with foodstuffs:

1. Substances evaluated by the European Food Safety Authority (EFSA) and used in compliance with SMLs or other restrictions, if any.
2. Substances approved in Partial Agreement member states, based on the evaluation of a toxicological dossier, which meets the current EFSA criteria.
3. Substances evaluated as food additives in compliance with SMLs or other restrictions.
4. Substances with a Product-type 4 biocidal function according to Regulation (EU) No 528/2012.

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Thank you for your attention



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