

## ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

## BONOLIVE

**Issue**

The Committee reviewed this application for the first time at the last meeting in April 2017. Queries were raised in relation to composition of the product. The applicant has now provided further information for the Committee's consideration. Members are invited to consider the response from the applicant and whether this addresses the questions raised in April. The Committee is asked to consider whether it recommends authorisation of the product.

**Background**

1. This application from BioActor B.V is for authorisation of Bonolive® (standardised extract prepared from the leaves of the olive tree (*Olea europaea* L.)) as a novel food ingredient under 258/97. At the April meeting the Committee requested further information in two key areas:
  - a) Specification
  - b) Undesirable substances
2. A letter was sent to the applicant communicating the Committee's points (**Annex A**). The applicant has now provided a response to the Committee's questions (**Annex B**) and provided accompanying documents (**Annex C - E**).

**Public comments**

3. In line with the Agency's openness policy, the application dossier was published on the Committee's website for a twenty one day public consultation. The public comments received have been summarised in **Annex F** for the Committee's consideration.
- a) **Specification**
4. At the last meeting the Committee requested a full specification for Bonolive® and details on other key components in the product. In relation to the proximate analysis the Committee commented that the figures reported for polyphenols should not be categorised as carbohydrates and were inconsistent with the values reported.
  5. The applicant has prepared a revised specification for Bonolive® and this is presented in Table 1 of the response (Annex B). The applicant has revised

the proximate analysis for Bonolive® and ensured that the values reported for carbohydrates are of the standard format and this is presented in Table 2 of the response (Annex B). With regards the Committee's query of potential variation of the novel food, the applicant has explained that the olive leaves used to produce Bonolive® are collected from the Mediterranean region only and will only use leaves from the first pruning (February).

#### **b) Undesirable substances**

6. The Committee previously sought reassurance on the potential presence of pesticide residues and details on harvesting of the novel food. The applicant response notes that as the leaves will be from the first pruning it very unlikely that the novel food will be exposed to pesticides and the described routine pesticides screen will be carried out.

#### **Committee Action Sought**

- a) The Committee is asked whether the response from the applicant is sufficient to address the questions raised in February 2017.
- b) If not, the Committee is asked to indicate what feedback should be given to the applicant.

**Secretariat  
April 2017**

#### **Annexes and Appendices attached**

Annex A - Letter sent to applicant following February 2017 meeting

Annex B - Applicant's response

Annex C - European Pharmacopoeia Monograph for Olive Leaf

Annex D - HPLC Chromatograms for 3 representative batches of Bonolive®

Annex E - HPLC Chromatograms for Toxicological Studies of Bonolive®

Annex F - Comments summary from public consultation of Bonolive® dossier.