COMMITTEE PAPER FOR DISCUSSION **ACNFP/129/02**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

BONOLIVE

Issue

The Committee reviewed this application for the first time at the February meeting. At the last meeting in April the Committee considered the applicant's response to queries raised previously and raised further comments.

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 the following key areas:

a) Composition

b) Representative samples

c) Intakes

d) Target Market

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**).

a) Composition

3. At the last meeting the Committee requested the chromatograms be clearly labelled and peaks be identified.
4. The applicant has a reviewed the chromatograms and ensured relevant peaks have been identified and labelled. This is presented in pages 2-8 of the response (Annex B).

b) Representative samples

5. The Committee previously sought reassurance on data sent by applicant in response to the Committee were representative samples of the batches tested.

6. The applicant response includes the internal sampling procedure that demonstrates the steps to ensure a representative sample is taken. This is presented on page 9 of the response (Annex B).

c) Intakes

7. The Committee requested information as to why the recommended dose of the novel food was close so to that of the one administered in the human studies. The Committee were also interested in understanding what evidence had the led applicant to comment that consumers of food supplements are unlikely to consume the novel ingredient from other sources.

8. The applicant has responded and provided information that this was because a realistic dose was given that took into account the margin of safety. The applicant has also detailed the type of product line intended for Bonolive® and the occurrence of over consumers. This is presented in pages 9-10 of the response (Annex B).

d) Target Market

9. The Committee also wished to understand the intended target group(s) and how the novel food will be marketed. In the applicant's response it was suggested that the target group was menopausal woman, as oppose to the more general over 50's market that had been presented previously.

10. The applicant has responded that the novel food is recommended for the wider over 50's market, however menopausal women may particularly benefit due to differences in that group. This explanation is detailed and presented on page 11 of the response (Annex B) and Annex E.

Committee Action Sought

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

Secretariat

July 2017

Annexes and Appendices attached

Annex A - Letter sent to applicant following February 2017 meeting

Annex B - Applicant’s response

Annex C – Sampling Procedure (English translation)

Annex D - Sampling Procedure Original – Available on request

Annex E – BioActor PowerPoint Presentation- Bonolive®