COMMITTEE PAPER FOR DISCUSSION **ACNFP/130/01**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

BONOLIVE

Issue

The Committee reviewed this application for the first time earlier this year at the February meeting. At the last meeting in July the Committee considered the applicant's response to queries raised previously. Additional points were raised that where feedback to the applicant.

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 July. 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 July meeting the Committee requested further information in the following key areas:

a) Composition

b) Allergenicity

c) Intended uses and Intakes

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**). **Annex B** contains sensitive information.

a) Composition

3. At the last meeting the Committee requested a detailed composition of the carbohydrate component of the product. This was to ensure that the novel ingredient was fully characterised.

4. The applicant has provided information on the typical composition of olive leaves using peer-reviews papers. This is presented in pages 2-3 of the response (**Annex B**) and in addition (**Annex C**).

b) Allergenicity

5. The Committee had suggested that the applicant consider the possibly of allergenicity in more detail. Of concern was the potential for allergic reactions to olive proteins in sensitive individuals, in particular potential reactions to lipid transfer proteins or other proteins contained in olive leaves.

6. The applicant response details the process of harvesting and production to explain the likelihood of a potential reaction being low. This is presented on page 3 of the response (**Annex B**).

c) Intended uses and Intakes

7. The Committee requested clarification as to whether the applicant intended to market the novel food ingredient in Foods for Special Medical Purposes (FSMP's) as there were inconsistencies between the application and the further information provided. If to be included in additional categories information on the margin of safety calculation for this category were requested.

8. The applicant has responded and provided clarification that they intend to market the product in FSMP's. The applicant has also detailed justification for the intended use level for this category. This is presented in pages 3-5 of the response (**Annex B**).

Committee Action Sought

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

Secretariat

September 2017

Annexes and Appendices attached

Annex A - Letter sent to applicant following July 2017 meeting

Annex B - Applicant's response (official sensitive)

Annex C – Referenced Journal papers