COMMITTEE PAPER FOR DISCUSSION **ACNFP/127/02**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

APPLICATION UNDER THE NOVEL FOODS REGULATION CONSIDERED UNDER ARTICLE 3(4) OF THE NOVEL FOODS REGULATION 258/97

Introduction

An application was submitted to the Food Standards Agency in December 2016 by BioActor B.V. for the authorisation of Bonolive® as a food ingredient under the novel foods regulation (EC) No 258/97. A copy of the application will shortly be placed on the Agency's website for public consultation.

Bonolive® is a standardised extract prepared from the leaves of the olive tree (*Olea europaea* L.). Bonolive® contain between 40 - 55% polyphenols, with the majority of these polyphenols being oleuropein. Bonolive® is proposed be used as an ingredient in a range of food categories, including yoghurts, fine bakery wares and beverages. The applicant proposes it for use in functional foods, food supplements and foods for special medical purposes (FSMPs).

The product is intended for the adult population over 50 years and will be used in food categories propped, targeting this sector. Bonolive® is made up of 94.8% carbohydrates, of which a significant part is polyphenols, with minimal fat and protein.

Bonolive® would be classified in Class 2 as a "complex NF from non-GM source" and would be further allocated under Sub-Class 2.1: "the source of the novel food has a history of food use in the Community".

I. Specification of the novel food

Information on this aspect is provided on p. 10-11 of the application dossier

The applicant has provided a specification for Bonolive®.

Specification Parameter	Specification
Appearance	Yellow to brown powder
Solubility	Freely soluble in water
Loss on drying	≤8%
Residue by calcination	≤9%

Olive polyphenols (=oleuropein)	40–55%

Bonolive® contains a minimal amount of fat (0.2%), protein (1.16%), and ash (1.67%). A large proportion of the carbohydrates (94.8%) are polyphenols. The extract is standardised to ensure that the novel food ingredient contains a minimum of 40% of the primary polyphenol, oleuropein and maximum of 55%.

Component	**Percentage**
Total Fat	0.2%
Carbohydrates	94.8%
Oleuropein	≥40%
Fibre	<0.1%
Ash	1.67%
Moisture	2.2%
Protein	1.16%
Sodium	0.172%
Sugars	<1%

II. Effect of the production process applied to the novel food

Information on this aspect is provided on p 17-20 of the application dossier

Bonolive® is manufactured by aqueous extraction using the leaves of the olive tree (*Olea europaea* L.). The production process complies with good manufacturing practices and quality control measures.

III. History of the organism used as a source of the novel food

Information on this aspect is provided on p 22-22 of the application dossier

Bonolive® is an extract prepared from the leaves of the olive tree (*Olea europaea* L.) The fruit of *O. europaea L.* is widely consumed as the common olive and is used to produce olive oil with the polyphenol compounds from the olive tree having been consumed for many years. The applicant also details examples of the use of olive

leaf extract in food supplements, a use which is not considered to be novel. In some of the available food supplements on the market the oleuropein content is considerably higher than the applicants proposed use level.

IX. Anticipated intake/extent of use of the novel food

Information on this aspect is provided on p 26-36 of the application dossier

Bonolive® is currently proposed for use various food categories including milk and dairy products, confectionary, cereal bars and food supplements. A detailed table of the proposed uses is provided in Table IX.A-1.

Estimates for the anticipated intake of Bonolive® have been determined using the proposed uses and use levels in combination with food consumption data from the EFSA Comprehensive database and the UK National Diet and Nutrition Survey (NDNS).

Looking at the refined estimates of intakes using data from the UK NDNS dataset, teenagers had the highest mean and 95th percentile intakes on an absolute basis of 109 mg/person/day (2.2 mg/kg body weight/day) and 333 mg/person/day (6.9 mg/kg body weight/day), respectively. Children had the highest intakes of Bonolive® on a per body weight basis with the highest mean and 95th percentile consumer only intakes of 3.2 mg/kg body weight/day and 9.3 mg/kg body weight/day, respectively. The applicant explains that the intake values in this age group are equivalent to just over 1 serving/day at the mean, and 4 servings/day at the 95th percentile.

Considering the target group, cumulative exposure from foods and beverages, as well as food supplements containing Bonolive® was determined for individuals aged over 50 years. The mean and 95th percentile intakes were calculated at 291 and 381 mg/person/day, respectively; equivalent to 4.1 and 5.3 mg/kg body weight/day for a 70 kg adult.

XI. Nutritional information on the novel food

Information on this aspect is provided on p 41 of the application dossier

Bonolive® is described as not nutritionally equivalent to other foods and does not intend to replace other foods in the diet. The applicant is marketing Bonolive® an alternative source of olive polyphenols. The applicant details that Oleuropein is associated with many health benefits by acting as an antioxidant, antihypertensive, hypercholesteraemic as well as protecting the heart and improving bone health. The applicant has noted that they will be submitting a health claims according to Regulation (EC) No 1924/2006 for Bonolive® and bone health.

XII. Microbiological information on the novel food

Information on this aspect is provided on p 12-12 of the application dossier

Microbiological specifications and batch results are presented in Table I.B-1 and Table I.C-1.

XIII. Toxicological information on the novel food

Information on this aspect is provided on p. 12 and 45-74 of the application dossier

Heavy metal specifications and batch results are presented in Table I.B-1 and Table I.C-1.

The applicant has described a series of toxicological studies using Bonolive®. The applicant carried out a 14 day oral gavage rat study to determine the dose range. The novel food ingredient was administered by gavage and was well tolerated with no mortalities or toxicologically relevant clinical signs seen as a result. There were increases in prothrombin observed in male rats and an increase in the percentage of basophil granulocytes observed in female rats. The applicant states these increases were not observed in a dose-dependent manner and not toxicologically-relevant.

There were increases seen in haematological observations, changes in clinical chemistry and increases in mean relative to body liver weight. The applicant explains these observations and summarises that the administration of Bonolive® did not result in adverse effects in the test animals, both in the main study and the satellite study. The NOAEL for the study was determined to be 1,000 mg/kg body weight/day, the highest dose tested, for both male and female rats.

The applicant details a study looking into mutagenicity of Bonolive® by way of a bacterial reverse mutation test; the study highlights that the novel ingredient did not exhibit any mutagenic potential. The applicant details a study looking into genotoxicity of Bonolive® using a mammalian erythrocyte micronucleus assay. The novel ingredient did not exhibit any chromosome aberrations in the study. No mortalities occurred in the study and it was concluded that Bonolive® does not have genotoxic potential in the mouse micronucleus test at doses of up to 2,000 mg/kg bw.

The applicant carried out a 90 day oral gavage rat study on Bonolive®. There were two deaths but both were considered to be caused by the gavage procedure and not due to the novel ingredient.

Committee Action Required

19. The Committee is asked whether the available data provide a satisfactory basis for evaluating the safety of this novel food ingredient.

20. If so the Committee is asked whether it is content to recommend approval of Bonolive® as an ingredient to be added to the range of foods specified.

21. If not, the Committee is asked to indicate what additional information or data would be required

Secretariat

January 2017

Annexes attached:

Annex A - Application Dossier

Annex B - Appendices