COMMITTEE PAPER FOR DISCUSSION **ACNFP/119/06**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

ALGINATE-KONJAC-XANTHAN POLYSACCHARIDE COMPLEX (PGX) DOSSIER 170

ISSUE

The Irish competent authority has prepared comments on an application for Alginate-Konjac-Xanthan Polysaccharide Complex (PGX) under the novel foods regulation (EC) No 258/97.

The Committee is asked whether it agrees with the initial opinion and whether it would like to make any further comments on this application. The Committee's advice will form the basis for the UK's formal response to the Commission.

Background

1. On 2 March the European Commission forwarded the Irish Food Safety Authority's initial opinion on an application made by InovoBiologic Inc under Article 4 of the Regulation, for Alginate-Konjac-Xanthan Polysaccharide Complex (PGX). The Commission has requested the views of Member States on the Irish CA's initial opinion. Member States have until 30 April 2015 to submit any comments and/or reasoned objections to the Irish assessment.

2. The application dossier is attached as **Annex A,** the Irish Initial Assessment Report is attached as **Annex B.** Further annexes providing the referenced papers are available on request**.** Annex A and B contain protected information.

This application

3. The novel ingredient is a viscous, water soluble complex of non-starch polysaccharides derived from plants, bacteria and seaweed. The individual polysaccharides that make up the PGX complex are currently authorised food additives in the EU; sodium alginate (E401), konjac-mannan flour (E425) and xanthan gum (E415).

4. In this initial application, the applicant proposed placing PGX on the European market as a novel food ingredient marketing PGX as a source of dietary fibre in dietary supplements as well as in a range of foods and beverages (represented in Table 10 of the dossier) with different incorporation choices proposed for the consumer.

Table 10: Food groups selected for PGX supplementation

Food Category	Recommended Daily Intake	Amount of PGX (g per 100g)
Yoghurt		1.1g
Dairy desserts and Puddings (eg ice cream, ice cream bars, frozen yoghurt, milkshakes)		0.67g
Breads (White and whole wheat)		5g
Biscuits / Cookies		8.3g
Cereals (eg flaked cereal, breakfast bars, granola type bar)		8.3g
Pasta / Noodles		1.79g
Cereal beverage		1.04g
Fruit juices and fruit smoothie-type drinks		1.04g
Single Serve Combination meals (eg Teriyaki chicken, lasagne)		1.0g
Dietary Supplement	Up to 15g/day	

5. The applicant has proposed a Recommended Daily Intake (RDI) of 15 g PGX/day (equivalent to 13.5g fibre). EFSA has suggested that 25g/day dietary fibre is adequate for normal laxation and the British Nutrition Foundation recommends a level of 18g/day for adults. The Irish CA opinion suggests that based on the intake assessment that high consumers of PGX containing products and supplements may exceed the EFSA level of dietary fibre adequate for normal laxation but as these are conservative estimates this is suggested to be unlikely.

6. Konjac glucomannan jelly sweets have been banned in the EU since 2003 due to a link with choking deaths. The applicant comments that the delayed viscosity of PGX should prevent the choking hazard of PGX in dietary supplement form, as the outer casing shields the fibre from water before reaching the stomach. Whilst information regarding the risks in supplement form is addressed, this information is not provided for all the proposed food uses.

7. The applicant has proposed labelling to warn that the product should not be used by children and people with swallowing difficulties. They suggest that diabetics, people on cholesterol lowering medication and pregnant or breast feeding women should consume the product only after seeking medical advice.

8. The applicant has considered the ADME mentioning it may slow or decrease the absorption of vitamins, nutrients and medication, whilst also assisting in weight control and appetite suppression, which has been noted in the context of eating disorders. The applicant comments that post-marketing surveillance of PGX in the US has seen no adverse drug reactions reported.

9. The Irish competent authority raised concerns that there is not a defined market with this novel food. They note that while the product is not to be consumed by children some of the proposed uses (dairy desserts, puddings and biscuits) are more likely to be consumed by children relative to other food categories.

COMMITTEE ACTION REQUIRED

10. Members are asked whether they agree with the initial opinion from the Irish Authorities and whether they wish to make any comments on the application.

11. The Committee's advice will form the basis for the UK's formal response to the opinion of the Irish Competent Authority.

Secretariat

April 2015

Annexes attached:

Annex A Application for the approval of Alginate-Konjac-Xanthan Polysaccharide Complex (PGX)

Annex B Initial Opinions of the Irish Authorities