

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

PHYTOSTEROLS FROM XI'AN HEALTHFUL BIOTECHNOLOGY

ISSUE

Xian Healthful Biotechnology is seeking the view of the UK competent authority on the substantial equivalence of their phytosterol ester product to those placed on the market by Archer Daniels Midland. At the last meeting members requested further information on which to base their assessment. This information was provided along with a draft opinion by correspondence. The Committee is invited to consider the revised draft of the opinion and whether it considers substantial equivalence has been demonstrated.

Background

1. In 2004, Archer Daniels Midland (ADM) gained authorisation for use of its phytosterols as a novel ingredient in the following products: yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products.
2. Under Article 3(4) of the Novel Foods Regulation (EC) 258/97, the Chinese company Xi'an Healthful Biotechnology is requesting an opinion from the UK Competent Authority (CA) on the equivalence of their phytosterols with phytosterols sold by ADM, for use in the same range of products.
3. According to Article 3(4) of (EC) 258/97, the notification procedures applies to "foods or food ingredients...which on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies...are substantially equivalent to existing foods or food ingredients as regards to their:
 - Composition
 - Nutritional value
 - Metabolism
 - Intended use, and
 - Level of undesirable substances contained therein."
4. The Committee reviewed this application at the January teleconference, February and April meetings seeking clarifications on specifications of the novel food, the effect of the production process applied to the novel food and the level of undesirable substances. Feedback from the consultation with members suggested that these questions have largely been addressed and

the opinion for the product can be progressed. The revised draft opinion is at **Annex A**.

5. To assist in further developing the opinion, the response from the applicant circulated by correspondence is provided again in **Annex B** as has the summary of the composition of previous phytosterol products by the UK **Annex C**. A consultation on the opinion has taken place and the public responses will be tabled at the meeting.

Committee Action Required

- The Committee is asked to consider the text of the draft opinion and to suggest any amendments.
- The draft opinion has been published via the Agency's web-site for the usual 10-day public consultation. After the Committee has considered any public comments and its opinion is finalised, the final opinion will be forwarded to the applicant to notify to the European Commission.

**Secretariat
June 2017**

Annexes attached:

Annex A – Draft opinion for the Committee's input.

Annex B - The applicant's response to the request for further information.

Annex C – Summary of composition of previously authorised phytosterol ingredients in the UK

Annex C - Summary of composition of previously authorised phytosterol ingredients in the UK

Fatty acids as a percentage	Specification from 2004/335EC	Tall oil based			XHB	Soya oil based			
		DDO	Prima/DRT*	Forbes		Lipofoods	Naturis	Cognis	Triple crown
β-sitosterol	< 80 %	81.8-86.3	75.9-76.6	40-71	44.13-45.82	40.0-44.0	55.17 - 55.7	45.5-52.7	48.4-49.3
β-sitostanol	< 35 %	10.2-11.1	11.1-11.6	9.0-31.0	0	0	3.69-3.72	2.1-3.5	0
campesterol	< 40 %	5.5-6.2	8.0-9.3	6.0-21.0	25.03-26.12	23.4-26.0	27.29 - 27.79	23.4-28.6	25.5-27.2
campestanol	< 15 %	0.7-0.8	1.2-1.1	2.0-11.0	1.36-1.42	0	1.28-1.4	0.6-0.7	0
stigmasterol	< 30 %	0.5-0.9	0	0-1.0	25.21-26.31	23.6-26.0	3.55	14.4-19.0	16.8-22.7
brassicasterol	< 3 %	0	0	0	0.66-0.79	1	0	2.3-2.9	2.0-2.8
other sterols/stanols	< 3 %	0	2.4-2.5	0†		<3	2.94	2.9-3.1	0.6-1.2

* DRT produce the phytosterols by Primapharm

† minor sterols - 5.0-15.0