

Regulatory perspectives on the first EFSA-approved novel microbes

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Abstract

Regulatory requirements in the European Union have become more rigorous with the establishment of the European Food Safety Authority (EFSA), which was tasked to conduct scientific assessments of the highest international standard for evaluating the safety of novel foods and the efficacy and health claims for foods.

Since the establishment of the novel foods Regulation (EC) No 258/97, two new novel microbes have been approved in Europe (*Akkeransia muciniphila* and *Bacteroides xylanisolvens*). Due to the challenging evaluation basis both bacteria were approved in the inanimate format to secure safety assessment. Until now no claim applications for the two strains have been submitted yet. Further, no health claims for probiotics have been approved since Regulation (EC) No 1924/2006 have been enacted. The standing Committee on the Food Chain and Animal Health in the guidance document on health claims, has in a memorandum noted that the requirement for a health benefit in the definition of the terms probiotic and prebiotic, using these terms on food labels constituted a *de facto* health claim. They therefore determined that these terms could not be used on food labels in the absence of a health claim approved by EFSA (https://ec.europa.eu/food/system/files/2016-10/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf). Similar logic will likely be applied to synbiotics and postbiotics such as the biotics. This approach has restricted information to consumers on biotics, while at the same time has allowed health claims for example for vitamins based on historical evidence rather than randomized controlled studies as is required for other health claims.

An annually reviewed system of Qualitative Presumption of Safe (QPS) assessment of microbes and biologicals approved in food has been established by EFSA Biohazard Panel to serve as the basis of safety evaluation (<https://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps>). This highly regarded approach serves globally as an example of safety assessment of

microbes at species level. To complete the picture, neither *Akkeransia muciniphila* nor *Bacteroides xylanisolvens* in their viable form are included in the QPS list as the safety at species could not have been established.