Hi Diane,


In general, the development of the Monograph was informed primarily by FAO/WHO guidance on the evaluation of probiotics in food (FAO/WHO 2006) and by a focused review of the available literature, cited in the Monograph. There are significant weaknesses in the available literature that make comparisons between products and studies challenging. In particular, in vitro determinants of probiotic activity in humans have not been reliably demonstrated or validated. For this reason, the Monograph lists species that contain one or more strains that have been reported to possess probiotic activity and requires that strains included in products be demonstrated effective probiotics in humans in order to qualify for one or more of the general health claims listed.

The Probiotics Monograph does not currently take into account the principles of the European Qualified Presumption of Safety (QPS) process, which are scientifically sound and could be quite useful to other regulators, given the current state of the literature. The European Food Safety Authority has adopted the QPS process and committed to conducting periodic reviews of the QPS List. I've included citations to both the initial description of the QPS process and the most recent revision of the QPS list.

We are currently preparing a communiqué for stakeholders regarding the regulation of probiotics and other products containing live microorganisms in Canada. This communiqué will discuss some of the current issues facing NHPD with regard to these products and our plans to address them temporarily in the short term and more permanently in the longer term. We expect this message to be sent in the very near future but I'm afraid I can't comment on its contents until it has been released. I will be able to provide more details at that time.

Please don't hesitate to contact me if I can be of any further assistance in this matter.


EFSAs Panel on Biological Hazards (BIOHAZ), 2009. Scientific Opinion on the maintenance of the list of QPS microorganisms intentionally added to food or feed (2009 update). EFSA Journal, 7(11), 1431. DOI: 10.2903/j.efsa.2009.1431
Kindest regards,

Daniel Buijs, MSc
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