8. There are 55 probiotic products with registered NAPPI codes available to pharmacies and health shops. Various independent investigators, among whom is Dr Temmerman from the University of Ghent, have analysed many different probiotic products, of which the trade names are cited in the references.[5,10-12] In our opinion, using trade names is upfront, honest, and enables clear communication with the health care profession and the consumer needing to be educated to make a decision about products that contain a number of difficult-to-pronounce bacterial names (unlike products containing a generic active like 'paracetamol').

We contend that it is the manufacturer's and distributor's minimum responsibility to ensure that their product complies with its label claim, and that it is the right of the health care worker as well as the consumer to know that the probiotic product recommended or purchased contains what it claims to contain. Accurate strain identification and viable count are paramount. Proof of label claims would provide an appropriate starting point for the industry to assist regulatory bodies in drawing up guidelines for trustworthy probiotic products. What needs to follow is a comparative review of the various claimed health benefits and published literature of the different probiotic strains.

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Probiotics — consensus of analysis

To the Editor: I have some important issues to raise with regard to the paper by Elliott and Teversham[1] and the rebuttals and opinions emanating from it.

While traditional starter cultures used in the dairy industry are selected for their ability to rapidly produce desirable organoleptic qualities of cultured dairy products, probiotic bacteria are selected for the potential to provide specific health or nutritional benefits following consumption. It must be realised that such a selection addresses several criteria including safety, technological and functional aspects.[2] The latter aspect has been extensively studied and reviewed, and the editorial 'Probiotics — how functional are they?' by H J Koornhof in the April *SAMJ*[3] clearly demonstrates the paramount fact about probiotics: their functionality in terms of health benefits to man and animal.

Two frequently overlooked and ignored aspects of safety and technological difficulties remain. The safety of probiotic strains is of major importance and guidelines for the safety assessment have been addressed in several articles.[4-6] The prerequisite of microbiological safety is the *identification of the strain*. The current state of evidence includes that probiotic effects are strain-specific, meaning that correct identification of the strain level is important to link a strain to a specific health effect as well as to enable accurate surveillance and epidemiological studies.[7] Furthermore, the origin of the strain and its potential GRAS (Generally Regarded as Safe) status,[8] antibiotic resistance profile and possible adverse side-effects are a few of the many issues to be addressed in the process of pre-marketing a probiotic.

To succeed in promoting the consumption of probiotic products, the food industry has to meet the demands of the consumer: in other words all probiotic foods should be safe, functional and attractive to the senses. Before probiotic strains can be delivered to consumers, they must first be capable of being included into industrial fermentations. Next, they need to survive and retain their functionality during storage as frozen or freeze-dried cultures as well as in the commercial food products to which they are added. Finally, the packaging material and storage conditions are important factors influencing the quality of the probiotic product during its shelf life. In most cases, the probiotic properties are affected by the way in which the strain or culture has been produced,[9] meaning that each strain and its production process should be characterised extensively in order to enable an effective probiotic product to enter the consumer market.

Regulatory and product labelling issues in the functional foods area (probiotics are not considered separately in this field) primarily involve two concerns: safety and assuring that product labelling and promotion, while communicating the

healthful effects of the product, is not misleading. This second item involves regulation of health claims. In general, a health claim can be defined as a direct, indirect or implied claim in food labelling, advertising and promotion that consumption of a food carries a specific health benefit or avoids a specific health detriment.[10] Regulations are far from unanimous worldwide, and with regard to certain aspects have evolved better for animal feed than for human nutrition.[11]

Besides legislation concerning health claims and labelling issues, effective on the pre-production phase, suitable legislation should be established addressing **quality control** during and after the production process. It is clear that regulators worldwide set priority at the health claim level, and the fact that this topic is far from established indicates that quality control legislation is still in its infancy. The acronym 'GMP' (good manufacturing practice) is used internationally to describe a set of principles and procedures which, when followed by manufacturers of mainly therapeutic goods, helps ensure that the products manufactured will have the required quality. A basic tenet of GMP is that quality cannot be tested into a batch of product but must be built into each batch of product during all stages of the manufacturing process. Various codes, guides and regulations relating to GMP have been published by different countries and trade blocks. For example, the European Union has published a GMP Guide for Medicinal Products. Most countries use compliance with a specified GMP requirement as the basis for licensing manufacturers of medicinal products and medical devices. *This GMP is now being extrapolated towards functional food manufacturers, although no definitive guidelines have been set up yet, and quality control is still entirely in the hands of the manufacturer, who often lacks the required expertise.*

In general, a comprehensive approach to shelf life of probiotic bacteria is tied to maintenance of efficacy. This implies knowledge of responsible factors and how they are affected by shelf life. Assuming that efficacy is tied to viability, the literature suggests that the performance of probiotic-containing products with regard to shelf life is mixed.[10] These studies provide 'snapshot' images of commercial products, some with little knowledge of storage history, or the analysis of a limited number of (national) products using sometimes doubtful identification methods.[8,12-14] *The need for a definitive legislation setting guidelines for quality control by manufacturers as well as by independent research groups is urgent and of utmost importance*, as indicated by the Thematic Priority 'Food Quality and Safety' of the Sixth Framework Programme.[15] *These guidelines should state modern standardised analysis methods in order to facilitate comparison on an international level.*

Whereas the majority of research groups worldwide have

focused on the elucidation of clinical health benefits and underlying mechanisms of probiotics, I chose to focus on the development of the abovementioned standardised analysis method. After 6 years of intensive research, with the aid of in-house renowned experts in the field of bacterial taxonomy, it is my opinion that the polymerase chain reaction-denaturing gradient gel electrophoresis (PCR-DGGE) methodology designed by myself and a team of expert colleagues shows reliable and reproducible output. It is important to realise that a standardised method for the general evaluation of probiotic products will face difficulties in matching the specificity of tests designed for the detection of one single strain or product. However, the PCR-DGGE method used in the study by Teversham and Elliott has been generally accepted through publication in renowned international peer-reviewed journals[16-22] and is also applied by other research groups.[23] It shows highly reliable results for the identification of bacteria in probiotic products, although quantification still depends on cultivation media, generally known to be subject to bias. Future developments of the method will focus on modern techniques, such as real-time PCR for quantification and reverse transcriptase PCR to determine the metabolic activity of the strains in the product and in *situ*.

In conclusion, it is crucial that various parties (companies, scientists, government, journalists) collaborate through *healthy criticism and communication*, in order to realise the one important goal: delivering good quality probiotic products to the demanding and interested consumer, before they lose confidence and the probiotic market drops to insignificant and non-restorable levels.

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Probiotics — the traveller's dilemma

To the Editor: We note with interest — and some confusion — a point made by Paul Anley of Pharma Dynamics in his letter to *SAMJ*.[1]

He questions the method of transport of probiotics sent to Belgium for an evaluation study. His products, he states, are 'particularly sensitive to atmospheric conditions and extremes of temperature' and were 'transported from South Africa under uncontrolled conditions.'

Are these not the very products recommended for the overseas traveller, to help alleviate the dreaded traveller's diarrhoea? How then should holidaymakers carry their medication?

One wonders too how these products withstand the rigours of their initial journey to South Africa and along the supply chain into the bathroom cupboard.

We trust the less robust probiotics on the market carry a warning on the label that they should be transported under strictly controlled conditions and not be subjected to extremes of temperature or air pressure.

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