



**SAAFoST**

**The South African Association for  
Food Science & Technology**

---

Minister of Health  
Private Bag X828  
Pretoria  
0001  
Attn Chief Director: Medicines Regulatory Affairs

06/10/2004

Dear Sir / Madam,

**Proposed Amendments to the General Regulations Made in Terms of the Medicines and Related Substances Act (Act 101 of 1965)**

The South African Association for Food Science and Technology (SAAFoST) is the professional body for South African food scientists and technologists. We have over 1400 members employed in academic institutions, research institutes, state departments and the food industry, and our key function is to support our members by promoting sound scientific practices in relation to food. Among the functions carried out by our members is the management of scientific issues relating to regulatory control of foods. We therefore feel we are in a good position to respond to the request for comment on the above amendments published on July 16<sup>th</sup> 2004, as many of these will have a significant impact on the regulatory control of foods.

**We fully support a comprehensive and well-managed system of regulatory control for foods in South Africa.** We are however concerned that the proposed amendments could potentially bring a very large number of substances which have historically been classified as foodstuffs into the category of medicines. We do not believe this was the intention when these amendments were drafted but believe it is necessary to remove potential ambiguity of interpretation. We refer to the Foodstuffs Cosmetics and Disinfectants Act and Regulations, 54/1972 which defines a foodstuff as "any article or substance (except a drug as defined in the Drugs Control Act 1965 [Act no.101 of 1965]) ordinarily eaten or drunk by man or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substance". The Medicines Act defines a medicine as "any substance or mixture of substances in the use or proportion to be suitable for use or manufacture or sale for use in (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man;

or (b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine”.

**We believe that it is thus possible to draw a distinction between foodstuffs and medicines.** We would maintain that the primary function of foods remains that of satisfying hunger while providing essential nutrients to those consuming them. To this end, we would suggest that products such as fortified foodstuffs and those foods offering health benefits in addition to simply satisfying hunger and providing essential nutrients should remain classified as foodstuffs. However we believe that products such as nutritional supplements and slimming aids, which are consumed specifically for the purpose of achieving a real or perceived health benefit, should not be classified as foodstuffs. It may be desirable to place this latter type of product in some form of intermediate category between foodstuffs and medicines but we believe it would be inappropriate for us to comment further in this regard as it is outside our area of expertise.

In regard to those foods which do offer specific nutritional and health benefits, we believe that there has been a substantial increase in consumer awareness in this area in recent years, and that there is a very real need for products of this type to be made available to South African consumers. However, in order that consumers be adequately protected and that they receive accurate information on the foods they consume, **we fully acknowledge that adequate regulation in this particular area is necessary.** In this regard we would draw your attention to the proposed amendments to the Regulations Relating to Labeling and Advertising of Foodstuffs of the Foodstuffs Cosmetics and Disinfectants Act. These amendments were published for comment on August 8<sup>th</sup> 2002 (Notice R. 1055) and one of their primary objectives is to ensure that correct and properly substantiated information relating to the nutritional content and potential health benefits of foodstuffs is made available to the public. Further extensive consultation has been undertaken by the Directorate of Food Control in regard to these amendments and it is believed that a second draft of the amendments is to be published shortly. **We believe that these amended regulations will result in a fully acceptable degree of regulatory control** in regard to the nutritional and health benefits of foodstuffs provide acceptable information to consumers and prevent abuses by unscrupulous food manufacturers. We further believe that the Directorate of Food Control possesses the specialist technical knowledge of food that is necessary to regulate foodstuffs and that **the proposed incorporation of any foodstuffs within the provisions of the Medicines & Related Substances Act will place a substantial additional administrative burden** on the Medicines Control Council while potentially duplicating the functions of the Directorate of Food Control.

We would also bring to your attention the role of the global food legislative advisory body Codex Alimentarius. This is a body operating under the auspices of the World

Health Organisation and the Food and Agricultural Organisation of the United Nations. Its function is to encourage standardization of global food regulatory standards with a view to reducing legislative complexity and promoting free global trade of foodstuffs. Liaison with Codex Alimentarius for South Africa is managed by the Directorate of Food Control. We believe that the **re-classification of any foodstuffs as medicines would be contrary to the principles of Codex Alimentarius and are not aware of any other country in the world where this has been done.** In addition,

Finally it is the view of those of our members working in the food industry that **the level of regulation applicable to medicines is simply not practical when applied to foodstuffs.** The cost of implementing the measures required by the Medicines and Related Substances Act would be substantial and would in all probability be passed on to consumers. There is a strong view that the Foodstuffs **Cosmetics and Disinfectants Act, and in particular the amended Regulations on Labeling and Advertising referred to above, provides a far more practical and cost-effective alternative for the regulation of foodstuffs with specific health and nutritional benefits, while still providing a fully acceptable level of protection to the consumer.**

**In summary we would suggest that foodstuffs be specifically excluded from the proposed amendments to the General Regulations** made in Terms of the Medicines and Related Substances Act (Act 101 of 1965). We suggest that this be done by inserting a clause excluding foodstuffs as defined in the Foodstuffs Cosmetics and Disinfectants Act. We would be happy to meet with the relevant staff members of the Department of Health to discuss the matter further should this be considered of value, as we believe we are in a position to contribute constructively and objectively towards a satisfactory resolution of this matter.

Yours sincerely

OJF  
Owen Frisby  
Executive Director  
Tel: (012) 346 2091