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27<sup>th</sup> June 2003

The Hon. Trish Worth MP  
Parliamentary Secretary to the Minister for Health and Ageing  
House of Representatives  
Parliament House  
Canberra ACT 2600

Dear Ms Worth,

**Re: Health and related claims – biomarker claims policy options**

Thank you for your phone call on Wednesday 25<sup>th</sup> June 2003. Further to our conversation, I am writing to you to clarify the Australian Consumers' Association's position on health claims policy, specifically in relation to the biomarker policy options.

Historically, the ACA has been against health claims for a variety of reasons. While industry argues that health claims will help consumers to make healthy food choices, thereby improving their health, the ACA disagrees with this view. In fact ACA feels that health claims have the potential to confuse consumers and undermine public health activities by distorting consumers' perceptions about a healthy diet and create the impression that specific food products have the potential to affect, improve or manage their health or disease state. The introduction of health claims is being driven by industry interests and not consumer demands.

For these reasons the ACA has remained conservative in its approach to health claims, and this is also the case with respect to biomarker claims. Of the three policy options relating to biomarkers, Option A is the ACA's preferred option, as it will see any claim relating to a biomarker classified as a high-level claim, and treated with what we feel is the necessary degree of caution. Biomarker claims should be treated with a similar level of caution as claims about specific diseases or health conditions. Only high-level claims will be subjected to pre-market assessment, medium-level and general-level claims will not. Option A will also allow for more effective regulation of biomarker claims as all biomarker claims will be subjected to pre-market assessment.

In ACA's view any claim about biomarkers should not be considered medium-level regardless of whether it is referring to the management of a biomarker in the context of a healthy person (i.e. policy option B) or the improvement/management of a biomarker in general (i.e. policy option C). Any claims referring to a biomarker should be examined with extreme caution and currently only a high-level classification would ensure any level of pre-market assessment.

In reality, consumers would not distinguish between an Option B claim and an Option C claim. They will see a reference to a biomarker eg cholesterol, and draw the same conclusion – that a particular food will help their cholesterol level regardless of whether they have a cholesterol problem, or whether that particular food is consumed in the context of a healthy diet.

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Options B and C would make regulation and enforcement extremely difficult. If biomarker claims are not subjected to pre-market assessment the only monitoring activity will be post-market surveillance and enforcement. This will result in the 'watchdog' and relevant jurisdictions being responsible for ensuring compliance. Unfortunately, we believe that biomarker claims (and health claims in general) will be subject to industry misuse and abuse, and in this instance, taking action after the damage has been done will not be a successful means of managing these claims.

If there are any reservations about biomarker claims, and we and others have substantial reservations, it would be wise to employ the most cautious approach, i.e. Option A. While it is possible to relax regulations should they prove to be unnecessarily restrictive, it will be much more difficult to reign in the food industry should regulations prove not to be strict enough.

We have learnt from the recent events in the complementary medicines industry, that such products and their related claims need to be treated with complete caution and must be strictly monitored. Under the proposed health claims policy the majority of claims will not be subject to pre-market assessment. Instead, it will be the responsibility of industry to hold evidence that a particular health claim can be substantiated, and up to the states and territories and the health claims 'watchdog' to monitor general and medium level health claims. In ACA's opinion, it would be irrational to replicate these experiences in relation to health claims.

I hope that you find this a helpful summary of our position on the biomarker issue and representative of our recent conversation. I appreciate the opportunity to discuss this with you. If you would like to discuss this further please do not hesitate to contact me on (02) 9577 3375.

Yours sincerely,

**Clare Hughes**  
**Food Policy Officer**