

Supporting document 7

Health Claims Management Plan – an approach for the regulation of general level health claims (superseded)

P293 – Nutrition, Health & Related Claims

During the review of the regulation of general level health claims, an outcomes-based approach, whereby a food business must have a health claims management plan (the Plan) in order to make a general level health claim, was considered.

Under this approach, a food business could not make a general level health claim unless they had a health claims management plan (the Plan) which demonstrated how they intended to meet the outcomes described in the Standard. Before marketing a food with a specific general level health claim, the food business had to action the Plan, putting together a dossier of information and evidence, including substantiation of the food/property-health relationship in the manner detailed in the Plan. The food business also had to demonstrate how the other requirements of the Standard were met. Refer to Figure 1 for a process flow diagram describing this approach.

The Standard would set out the minimum requirements for what must be included in a Plan, and require that a correctly completed Plan is recognised or approved by the jurisdictions.

In summary, the Standard would provide that:

- a food business must not make a general level health claim unless the relationship between the food or property of the food and the health effect that forms the basis of the claim has been substantiated
- a food business must not make a general level health claim unless the food business has a Plan
- the Plan must detail how the requirements of the Standard will be or are being complied with by the food business
- the Plan is approved or recognised by the relevant authority
- the general level health claim and the Plan comply with the requirements of the Standard
- the food business complies with its Plan in order to derive or generate a general level health claim.

The Standard would also provide that a general level health claim must not be:

- presented in a way which is misleading or deceptive
- made about a food which does not meet the nutrient profiling scoring criterion
- made about an ineligible food.

Guidelines and Plan templates could be developed to assist the food industry to develop a compliant Plan and achieve consistency across the jurisdictions. Three types of Plan templates were proposed, which differed according to the method of substantiation, as follows:

- Type 1 – use of a ‘pre-assessed’ food/property-health relationship listed in guidance material or in the Plan template. FSANZ had prepared a list of 90 of these types of relationships.
- Type 2 – food/property-health relationships approved by specified overseas regulatory authorities e.g. US Food and Drug Administration, European Commission.
- Type 3 – other methods which are not Type 1 or 2 methods of substantiation e.g. systematic reviews. Type 3 substantiation was focused on new food/property health relationships and would be more scientifically demanding on both food businesses and the regulators.

For Type 1 and Type 2 Plans, the intention was that jurisdictions would recognise a correctly completed Plan in accordance with a template, which must be made available by the food business on request.

For Type 3 Plans, it was suggested that the Plan might be approved by the relevant jurisdiction before the food business actions the Plan. In addition, for Type 3 Plans it was proposed that the dossier be assessed by FSANZ (or another expert body) prior to the claim being made.

Figure 1: Health Claims Management Plan - An approach for the substantiation of general level health claims (GLHC)

