

Food Standards (Proposal P1025 – Code Revision) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on 1 March 2016.

Dated 25 March 2015



Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC 96 on 10 April 2015.

Schedule 6

Required elements of a systematic review

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

This Standard, together with Schedule 4 and Schedule 5, relates to Standard 1.2.7 (nutrition, health and related claims), and sets out information for the purpose of that Standard.

Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014* (NZ). See also section 1.1.1—3.

S6—1 Name

This Standard is *Australia New Zealand Food Standards Code – Schedule 6 – Required elements of a systematic review*.

Note Commencement:
This Standard commences on 1 March 2016, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

S6—2 Required elements of a systematic review

For sections 1.2.7—18, 1.2.7—19 and 1.2.7—20, a systematic review must include the following elements:

- (a) A description of the food or property of food, the *health effect and the proposed relationship between the food or *property of food and the health effect.
- (b) A description of the search strategy used to capture the scientific evidence relevant to the proposed relationship between the food or property of food and the health effect, including the inclusion and exclusion criteria.
- (c) A final list of studies based on the inclusion and exclusion criteria. Studies in humans are essential. A relationship between a food or property of food and the health effect cannot be established from animal and in vitro studies alone.
- (d) A table with key information from each included study. This must include information on:
 - (i) the study reference; and
 - (ii) the study design; and
 - (iii) the objectives; and
 - (iv) the sample size in the study groups and loss to follow-up or non-response; and
 - (v) the participant characteristics; and
 - (vi) the method used to measure the food or property of food including amount consumed; and
 - (vii) confounders measured; and
 - (viii) the method used to measure the health effect; and
 - (ix) the study results, including effect size and statistical significance; and
 - (x) any adverse effects.
- (e) An assessment of the quality of each included study based on consideration of, as a minimum:
 - (i) a clearly stated hypothesis; and
 - (ii) minimisation of bias; and
 - (iii) adequate control for confounding; and
 - (iv) the study participants' background diets and other relevant lifestyle factors; and

- (v) study duration and follow-up adequate to demonstrate the health effect; and
 - (vi) the statistical power to test the hypothesis.
 - (f) An assessment of the results of the studies as a group by considering whether:
 - (i) there is a consistent association between the food or property of food and the health effect across all high quality studies; and
 - (ii) there is a causal association between the consumption of the food or property of food and the health effect that is independent of other factors (with most weight given to well-designed experimental studies in humans); and
 - (iii) the proposed relationship between the food or property of food and the health effect is biologically plausible; and
 - (iv) the amount of the food or property of food to achieve the health effect can be consumed as part of a normal diet of the Australian and New Zealand populations.
 - (g) A conclusion based on the results of the studies that includes:
 - (i) whether a causal relationship has been established between the food or property of food and the health effect based on the totality and weight of evidence; and
 - (ii) where there is a causal relationship between the food or property of food and the health effect:
 - (A) the amount of the food or property of food required to achieve the health effect; and
 - (B) whether the amount of the food or property of food to achieve the health effect is likely to be consumed in the diet of the Australian and New Zealand populations or by the target population group, where relevant.
 - (h) An existing systematic review may be used if it is updated to include:
 - (i) the required elements (a) to (f) above for any relevant scientific data not included in the existing systematic review; and
 - (ii) the required element (g) above incorporating the new relevant scientific data with the conclusions of the existing systematic review.
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