

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority had originally prepared Proposal P1030 to permit formulated supplementary sports foods, electrolyte drinks and electrolyte drink bases to carry health claims on their labels and in advertising; and to transfer the regulation of electrolyte drinks and electrolyte drink bases from Part 2.6 to Part 2.9 of the Code. The Authority had considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act and prepared a draft variation (the call for submissions (CFS) draft variation).

The Authority then called for submissions on the draft variation in 2014 under section 61 of the FSANZ Act and had regard to all submissions made during the CFS in accordance with subsection 63(2) of the Act. Consequently, the Authority had further considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act; and revised the scope and direction of the Proposal to limit its focus on the composition and labelling of electrolyte drinks. The Authority also proposed that the regulation of electrolyte drinks and electrolyte drink bases would remain in Part 2.6 of the Code and not be transferred to Part 2.9 as originally proposed. Following further consideration of the Proposal in accordance with Division 2 of Part 3, the Authority proposed a number of amendments to the draft variation.

The Authority undertook further consultation with stakeholders in May 2021 on the proposed amendments to the draft variation and has had regard to all submissions made during that consultation in addition to submissions received in 2014. The Authority then further considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act and approved the draft variation with amendments (the approved draft variation).

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation (also known as the Food Ministers' Meeting), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunseting provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunseting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the

instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunseting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation that amends Standards 1.1.2, 1.2.1 and 2.6.2 of the Code to enhance the regulation of the composition and labelling of electrolyte drinks and electrolyte drink bases. This includes amending the definition of 'electrolyte drink'; reducing the minimum level of carbohydrate; and setting out revised requirements and limitations for claims that may be made in relation to electrolyte drinks and electrolyte drink bases, such as nutrition content claims and health claims.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

5. Consultation

The Authority's consideration of Proposal P1030 included two rounds of public comment: a call for submissions issued in accordance with the procedure in Division 2 of Part 3 of the FSANZ Act; and a subsequent public consultation paper. The first detailed and sought submissions on: the Authority's assessment; the draft variation prepared as a result of that assessment; and associated reports. The second sought submissions on the Authority's further assessment after consideration of submissions received and on a proposed amended draft variation. Submissions were called for on 18 August 2014 and again on 28 May 2021; each for a six-week duration.

The Office of Best Practice Regulation (OBPR) had previously exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory changes proposed in response to the original Proposal (ID: 16662). As the Proposal had undergone significant change in direction since the CFS in 2014, FSANZ sought further advice from the OPBR, who subsequently confirmed they are satisfied that the amendments to the draft variation proposed post CFS are deregulatory and likely to only have a minor effect on consumers, businesses, and government (ID: 43269).

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Standard 1.1.2 – Definitions used throughout the Code

Item [1] of the Schedule to the variation amends the definition of ‘electrolyte drink’ in subsection 1.1.2—3(2).

The new definition is:

‘**electrolyte drink** means a drink formulated for the rapid replacement of fluid, carbohydrate and electrolytes during or after 60 minutes or more of sustained strenuous physical activity.’

Standard 1.2.1 – Requirements to have labels or otherwise provide information

Item [2] of the Schedule to the variation amends Standard 1.2.1. The item amends the reference in paragraph 1.2.1—8(1)(t) to declarations and information requirements in Standard 2.6.2 for electrolyte drinks and electrolyte drink bases as a consequence of amendments made to Standard 2.6.2 (see **item [3]** below), including the numbering of relevant provisions in that Standard.

Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks

Item [3] of the Schedule to the variation amends Standard 2.6.2 as follows.

Subitem [3.1] inserts the heading of the first of four new Divisions in Standard 2.6.2 after *Note 2* to that Standard: ‘**Division 1 Preliminary**’. Division 1 encompasses sections 2.6.2—1 and 2.6.2—2.

Subitem [3.2] replaces section 2.6.2—2 with a new section containing three new *Notes*, each of which sets out the definitions of certain terms from sections 1.1.2—2, 1.1.2—3 and 1.1.2—9 respectively.

This subitem also inserts the following Division heading after section 2.6.2—2: ‘**Division 2 Packaged water**’. Division 2 encompasses sections 2.6.2—3 to 2.6.2—5 inclusive.

Subitem [3.3] inserts the following Division heading after section 2.6.2—5: ‘**Division 3 Non-alcoholic beverages and brewed soft drinks**’. Division 3 encompasses sections 2.6.2—6 to 2.6.2—9 inclusive.

Subitem [3.4] replaces sections 2.6.2—9 to 2.6.2—13 inclusive, with new provisions: sections 2.6.2—9 to 2.6.2—18.

Section 2.6.2—9 requires that a food sold as a formulated beverage must be a formulated beverage. This is the same requirement as currently set out in section 2.6.2—13. As a formulated beverage is a non-alcoholic beverage, section 2.6.2—13 was moved up in the Standard (and renumbered accordingly) to be located with other provisions relating to non-alcoholic beverages and brewed soft drinks in Division 3 of the Standard.

This subitem also inserts the following Division heading after section 2.6.2—9: ‘*Division 4 Electrolyte drinks and electrolyte drink bases*’. Division 4 encompasses sections 2.6.2—10 to 2.6.2—18 inclusive.

Section 2.6.2—10 contains the following preliminary provisions applying to electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—10(1) sets out the definition of ‘prescribed electrolyte’ for the purposes of Division 4. ‘Prescribed electrolyte’ means any of the following:

- sodium;
- potassium;
- calcium;
- magnesium;
- chloride.

This definition has been provided because some of the substances listed as ‘prescribed electrolytes’ for the purposes of Division 4 are also ‘minerals’ for the purposes of requirements elsewhere in the Code.

Subsection 2.6.2—10(2) clarifies that for an electrolyte drink base, the compositional and declaration requirements in Division 4 apply to the electrolyte drink base as ready to drink.

Section 2.6.2—11 sets out the following compositional requirements for electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—11(1) requires that a food sold as an electrolyte drink or an electrolyte drink base must be an electrolyte drink or an electrolyte drink base respectively.

Subsection 2.6.2—11(2) sets out the mandatory compositional requirements for electrolyte drinks and electrolyte drink bases. This subsection requires that an electrolyte drink or electrolyte drink base must contain:

- no less than 10 mmol/L of sodium; and
- no less than 20 g/L and no more than 100 g/L in total of the following:
 - dextrose;
 - fructose;
 - glucose syrup;
 - maltodextrin;
 - sucrose; and
- no more than 50% of total carbohydrate as fructose.

Subsection 2.6.2—11(3) sets out the discretionary compositional requirements for electrolyte drinks and electrolyte drink bases. This subsection allows an electrolyte drink or electrolyte drink base to contain:

- calcium phosphates;
- potassium phosphates;
- calcium citrates;
- potassium citrates;
- sodium citrates;
- potassium carbonates, including potassium bicarbonate;
- potassium chloride;
- calcium chloride;
- sodium chloride;
- calcium lactate;
- magnesium lactate;
- magnesium sulphate.

Section 2.6.2—12 sets out the following labelling requirements for electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—12(1) provides that ‘Electrolyte drink’ is a prescribed name for an electrolyte drink and an electrolyte drink base.

The ‘prescribed name’ of a food is a term defined in subsection 1.1.2—2(3) [see **subitem 3.2** of the approved draft variation]. The labelling provisions in Standard 1.2.1 and section 1.2.2—2 require that, if a food has a prescribed name, that name must be used in the labelling of the food.

Subsection 2.6.2—12(2) requires the following information to be provided for the labelling provisions:

- the recommended volume and frequency of use (paragraph 2.6.2—12(2)(a)); and
- the nutrition information panel (NIP) must also declare the average quantity per serving and per unit quantity of all of the following (paragraph 2.6.2—12(2)(b)):
 - each type of monosaccharide present; and
 - each type of disaccharide present; and
 - subject to subsection 2.6.2—12(3) (see below), each prescribed electrolyte present (other than sodium), expressed in milligrams or both milligrams and millimoles.

‘Average quantity’ and ‘unit quantity’ are terms defined in subsection 1.1.2—2(3) [see **subitem 3.2** of the approved draft variation].

There are *Notes* to paragraph 2.6.2—12(2)(b).

Note 1 explains that labelling provisions are set out in Standard 1.2.1.

Note 2 explains that section 1.2.8—5 provides that packaged food (unless exempted) must include an NIP; and Standard 1.2.8 also contains other requirements relating to NIPs, for example, information that must be included and how to express that information in an NIP (see sections 1.2.8—6 and 1.2.8—7). This *Note* also explains that the requirements set out in paragraph 2.6.2—12(2)(b) *are in addition to* those other requirements.

Note 3 explains that subparagraph 1.2.8—6(1)(d)(iii) requires that an NIP must contain (among other information) the average quantity of sodium, expressed in milligrams or both milligrams and millimoles for a serving of the food and a unit quantity of the food.

Subsection 2.6.2—12(3) provides that the requirement in subparagraph 2.6.2—12(2)(b)(iii) applies only in relation to an electrolyte drink or an electrolyte drink base to which a substance listed in subsection 2.6.2—11(3) has been added.

The effect of both subparagraph 2.6.2—12(2)(b)(iii) and subsection 2.6.2—12(3) is that where a substance listed in subsection 2.6.2—11(3) has been added to an electrolyte drink or electrolyte drink base, the average quantity per serving and per unit quantity of each prescribed electrolyte that is present in the electrolyte drink or electrolyte drink base must be declared. These quantities are based on the *total amount* of a prescribed electrolyte that is present in the electrolyte drink or electrolyte drink base, i.e. the amount of the prescribed electrolyte derived from *all sources* added to the electrolyte drink or electrolyte drink base—i.e., derived from a substance listed in 2.6.2—11(3) and from any other substance such as an intense sweetener.

Section 2.6.2—13 sets out the following labelling requirements for electrolyte drinks and

electrolyte drink bases in small packages.

Subsection 2.6.2—13(1) clarifies that requirements in this section apply to an electrolyte drink or electrolyte drink base:

- that is in a small package; and
- about which a claim requiring nutrition information is made; and
- the claim relates to a prescribed electrolyte.

The terms 'small package' and 'claim requiring nutrition information' are defined in subsection 1.1.2—2(3) [see **subitem 3.2** of the approved draft variation].

Subsection 2.6.2—13(2) provides that for the labelling provisions, the required information includes the average quantity per serving of each prescribed electrolyte present, expressed in milligrams or both milligrams and millimoles.

There are two *Notes* to subsection 2.6.2—13(2).

Note 1 explains that labelling provisions are contained in Standard 1.2.1.

Note 2 explains that the requirements of subsection 2.6.2—13(2) are in addition to the requirements set out in section 1.2.8—14. Section 1.2.8—14 sets out requirements for food for sale in a small package where a claim requiring nutrition information is made in relation to the food.

Subsection 2.6.2—13(3) provides that paragraph 1.2.8—14(1)(b) does not apply to a claim requiring nutrition information that is made about a prescribed electrolyte. Paragraph 1.2.8—14(1)(b) sets out nutrition information requirements for food for sale in a small package where a claim requiring nutrition information is made about a matter listed in Column 1 of the table to section S13—2 (such as sodium or a mineral with a Recommended Dietary Intake). Subsection 2.6.2—13(3) provides that these nutrition information requirements do not apply when a claim requiring nutrition information is made about a *prescribed electrolyte* in an electrolyte drink or electrolyte drink base in a small package.

The *Note* to subsection 2.6.2—13(3) explains that paragraph 1.2.8—14(1)(b) sets out nutrition information requirements for food for sale in a small package where a claim requiring nutrition information is made about a matter listed in Column 1 of the table to section S13—2 (such as sodium or a mineral with a Recommended dietary intake (RDI)).

Section 2.6.2—14 contains the following prohibitions related to RDI information for electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—14(1) provides that an RDI must not be stated or declared in relation to an electrolyte drink or electrolyte drink base.

Subsection 2.6.2—14(2) provides that section 1.2.8—9 does not apply to an electrolyte drink or electrolyte drink base.

The *Note* to subsection 2.6.2—14(2) explains that section 1.2.8—9 relates to minerals with an RDI (among other things). As stated above, some of the substances listed as 'prescribed electrolytes' in section 2.6.2—10 are also minerals with an RDI for the purposes of section 1.2.8—9, for example, calcium and magnesium (see also the table to section S1—3).

Section 2.6.2—15 contains the following requirements and limitations for making nutrition content claims made about electrolyte drinks and electrolyte drink bases.

'Nutrition content claim' is defined in section 1.1.2—9 [see **subitem 3.2** of the approved draft variation].

Subsection 2.6.2—15(1) provides that a nutrition content claim must not be made about an electrolyte drink or electrolyte drink base unless both of the following conditions are satisfied:

- subject to paragraph 2.6.2—15(2)(b), the claim is made in accordance with Division 4 of Standard 1.2.7 (Requirements for nutrition content claims); and
- the claim is about any of the following:
 - sugar or sugars content; or
 - carbohydrate content; or
 - energy; or
 - the presence of one or more prescribed electrolytes.

'Sugar' is defined in subsection 1.1.2—2(2) and 'sugars' is defined in subsection 1.1.2—2(3) [see **subitem 3.2** of the approved draft variation].

Subsection 2.6.2—15(2) provides that if a nutrition content claim is made under subparagraph 2.6.2—15(1)(b)(iv) i.e., the claim is about the presence of one or more prescribed electrolytes:

- the claim must only state that the electrolyte drink or electrolyte drink base contains one or both of the following:
 - electrolytes (for example, 'Contains electrolytes');
 - a prescribed electrolyte that is present in the food, provided that the claim also states that the prescribed electrolyte is an electrolyte (for example, 'This food contains the electrolytes: calcium and sodium'); and
- any conditions for nutrition content claims in Standard 1.2.7 relating to a prescribed electrolyte present in the food do not apply to the nutrition content claim (this is because, as stated above, some substances listed as 'prescribed electrolytes' in section 2.6.2—10 are also 'minerals' for the purposes of requirements elsewhere in the Code, for example, Standard 1.2.7).

Section 2.6.2—16 contains the following requirements and limitations for health claims made about electrolyte drinks and electrolyte drink bases.

Subsection 2.6.2—16(1) provides that Standard 1.2.7 does not apply to a health claim made about an electrolyte drink or electrolyte drink base.

'Health claim' is defined in subsection 1.1.2—2(3) [see **subitem 3.2** of the approved draft variation].

Subsection 2.6.2—16(2) only allows health claims to be made if both of the following conditions are satisfied:

- the food has an average osmolality of 200–340 mOsmol/kg; and
- the claim is about any of the following:
 - rapid rehydration in association with words to the effect of 'after at least 60 minutes or more of strenuous physical activity';
 - rapid hydration in association with words to the effect of 'during at least 60

- minutes or more of strenuous physical activity’;
- contribution to the maintenance of performance by rapid hydration in association with words to the effect of ‘during at least 60 minutes or more of strenuous physical activity’.

Subsection 2.6.2—16(3) requires that where a health claim is made under subsection 2.6.2—16(2), the amount of time must be expressed only as a quantifiable amount of time. For example, ‘60 minutes’ or ‘sixty minutes’; ‘1 hour’ or ‘one hour’.

Subsection 2.6.2—16(4) clarifies that, subject to subsection 2.6.2—16(3), nothing in section 2.6.2—16 is to be taken to prescribe the words that must be used when making a health claim under this section. For example, one may state ‘exercise’ instead of ‘physical activity’.

Section 2.6.2—17 contains the following requirements for making a claim in relation to the tonicity of an electrolyte drink.

‘Claim’ is defined in subsection 1.1.2—2(3) [see **subitem 3.2** of the approved draft variation].

Subsection 2.6.2—17(1) only allows a claim to be made that an electrolyte drink is isotonic if the electrolyte drink has an average osmolality of 250–340 mOsmol/kg.

Subsection 2.6.2—17(2) requires that, for the labelling provisions, a declaration of the osmolality of the electrolyte drink, (expressed in mOsm/L) be made if a claim is made that an electrolyte drink is isotonic, hypertonic or hypotonic.

The *Note* to subsection 2.6.2—17(2) explains that the labelling provisions are set out in Standard 1.2.1.

Section 2.6.2—18 states that subsection 1.2.8—6(12) does not apply to a claim requiring nutrition information that is made in relation to salt or sodium in an electrolyte drink or electrolyte drink base.

The *Note* to section 2.6.2—18 explains that subsection 1.2.8—6(12) provides that, if a claim requiring nutrition information is made in relation to salt or sodium in a food product, the NIP for that product must include a declaration of the average quantity of potassium in accordance with section S12—3.

Transitional arrangements

The above variations will commence or take effect on the date of gazettal. See **clause 3** of the instrument of variation.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of the above variations. See **clause 4** of the instrument of variation.

Clause 4 provides a transitional arrangement where, during a 24 month transition period commencing on the date of gazettal, an electrolyte drink or electrolyte drink base may be sold if the electrolyte drink or electrolyte drink base complies with either the Code as in force without the amendments made by the approved draft variation; or the Code as amended by the approved draft variation. The intent is to provide a 24 month transitional arrangement that covers both stock-in-trade at the time of the commencement of the variations, as well as electrolyte drinks or electrolyte drink bases that are packaged, labelled and made available for sale before the end of the transition period.

