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UNLOCKING THE ENERGY OF THE AMAZON? THE NEED FOR A FOOD FRAUD POLICY APPROACH TO THE REGULATION OF ANTI-AGEING HEALTH CLAIMS ON SUPERFOOD LABELLING

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ABSTRACT

The prevention and control of 'food fraud', including false or misleading statements made about a product for economic gain, is now emerging as an important and discrete policy goal for governments and regulators in the interface between food and public health. The control and prevention of food fraud complements regulation to ensure microbial food safety. This article uses a case study of anti-ageing claims made in the labelling and advertising of açai berry superfood products to argue that Australia's new regulatory system for nutrient content and health claims on food (Australia and New Zealand Food Standards Code Standard 1.2.7) inadequately addresses 'food fraud'. This article argues that the over-reaching claims on açai product labelling will potentially mislead consumers and subvert public health messages in a context of 'gastro-anomy' (confusion over appropriate norms for eating) and 'healthism' (individual responsibility for making healthy choices). This conduct can usefully be conceptualised as food fraud. Second, the article argues that although the substance of Standard 1.2.7 is well designed to avoid food fraud, the fact that the standard allows food businesses to self-substantiate evidence when making some health claims undermines the protection offered. Australian food regulators need to articulate a more strategic and proactive approach to the prevention and control of food fraud.

I INTRODUCTION

Açaí (Pronounced ah-SAH-ee) is a little purple berry that originated in the Amazon rainforest of Brazil. This 'wonder berry' is considered to be one of the most powerful and nutritious super foods on the planet. It contains high levels of essential fatty acids (omega 3's in particular) known for their cardio and neuro-protective and anti-inflammatory effect. It is super rich in antioxidants to reduce cholesterol, contains 19 different amino acids to

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optimize brain signaling pathways, is rich in minerals and vitamins (especially calcium and vitamin E) for healthy hair, skin and nails. Açai is low in sugar so it won't alter blood sugar levels and is an excellent source of dietary fiber and natural energy.

So now you're probably thinking 'Surely something that good for me, can't possibly taste good.' Well, eating your own words has never been so delicious. When the berries are blended, we describe it as a fruit sorbet with hints of dark chocolate and red wine. What's not to like?

(Kiss the Berry the Açai Specialists)

In recent years a wide range of foods have been marketed as 'superfoods' from blueberries to broccoli to black pepper and bananas.¹ The term 'superfood' is popular in marketing but ambiguous in meaning. The term has no official definition and can be used to market a range of different foods 'all with intrinsic components that are believed to have beneficial health effects'.² The 'most well-known definition' refers to fruits and vegetables that are particularly rich in antioxidants, especially phytochemicals,³ which are often associated with anti-ageing health claims. Food businesses marketing foods as 'superfoods' have seen their sales figures rise. Blueberry sales reportedly doubled between 2005 and 2007 'following superfood claims'.⁴ In more recent years a range of new and exotic superfoods have been discovered and marketed with stories about their ancient origins and the ways they were used for health and wellbeing. These include goji, quinoa, chia and açai.

The consumer is promised that by ingesting these foods and various juices, powders, and tablets that include these foods, they too can unleash this power to protect themselves against cancer, heart disease, weight-gain, neurological disease, ageing and stress. The labelling of 'superfoods' with health, and specifically anti-ageing, claims may be particularly attractive to consumers in a social context in which they are anxious to care for their own health yet face a multiplicity of conflicting cultural norms and cues about how and what to eat.⁵ As one commentator points out, '[s]uch claims are typically associated with expensive boutique foods'.⁶ Yet much of the evidence for these claims is indirect or uncertain at best. Equivalent or greater benefits can generally be found in a consistent diet of more available and affordable fresh foods.⁷

This article argues that many of the claims made for superfood products could amount to 'food fraud'. Although the new Australia and New Zealand Food Standards Code (*the Code*) Standard 1.2.7 (*'Standard 1.2.7'*) prohibits overreaching health claims, such as those found on superfoods, it does not articulate a sufficiently strategic and proactive approach to controlling and preventing this type of conduct in the interest of consumers. Indeed, it allows industry the opportunity to undertake systematic reviews

¹ Caroline Williams, 'A Blueberry a Day ...' (2016) 231 (3085) *New Scientist* 26, 27.

² Joanne Lunn, 'Superfoods' (2006) 31(3) *British Nutrition Foundation Nutrition Bulletin* 171, 172.

³ See below nn 78–85 and accompanying text.

⁴ Emma Weitkamp and Torill Eidsvaag, 'Agenda Building in Media Coverage of Food Research: Superfood Coverage in UK National Newspapers' (2014) 8(6) *Journalism Practice* 871, 872.

⁵ See below nn 53–65 and accompanying text.

⁶ Tim Crowe, *Superfoods: More Like a Supermyth* (18 August 2012) Thinking Nutrition <<http://www.thinkingnutrition.com.au/superfoods-more-like-supermyth/>>.

⁷ See below nn 78–86 and accompanying text.

of scientific literature in the self-substantiation of food health relationships for general level health claims. The monitoring and enforcement of industry compliance with self-substantiation requirements are likely to be deprioritised by state food regulators in favour of the more urgent need to monitor food safety requirements.⁸

The first part of this article (Section II.A) introduces the concept of 'food fraud' as a policy goal for food regulation. 'Food fraud is a collective term' that encompasses not only 'the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging' but also 'false or misleading statements made about a product for economic gain'.⁹ Food fraud was traditionally a tortious wrong with a civil remedy in Australia and is now more proactively regulated via prohibitions on misleading conduct in the *Model Food Act 2000*. The control and prevention of food fraud is now emerging as an important and discrete policy goal for governments and regulators in the food and public health arenas.¹⁰ The EU in particular recognised the need for comprehensive food fraud control and prevention in the wake of the horse meat substitution scandal, and a 'fancy name' such as superfood cannot be used on food labelling unless it is accompanied by a regulated (or related) and pre-approved claim that explains why the food is good for consumers' health.¹¹ This article (Section II.B) uses the case study of the labelling and marketing of açai berry superfood products to show that overreaching and/or unsubstantiated health claims are observed on superfood products in Australia and that they constitute a risk to consumer protection and public health in a context of 'gastro-anomy' (confusion over appropriate norms for eating) and 'healthism' (individual responsibility for making healthy choices). Such claims should be prevented and controlled as examples of 'food fraud'.¹² Indeed the onus should lie on food businesses to ensure this information is not false, misleading or deceptive and compliant with requirements including scientifically substantiated to the standard provided in law.

The second part of the article critically assesses whether the Code's new *Standard 1.2.7* can effectively address potential 'food fraud' such as that observed on açai product labelling (Section III.A).¹³ *Standard 1.2.7* requires a high evidential threshold for health claims in line with best practice regulation in the EU. Thus, the substance of *Standard 1.2.7* is in theory capable of addressing this type of food fraud. In practice, however, the implementation and enforcement of *Standard 1.2.7* relies heavily on industry self-substantiation.¹⁴ This contrasts sharply with the EU where regulator pre-approval is required for all health claims on food labelling (Section III.B.1).¹⁵ In Australia, where implementation and monitoring of the federal Standards in the Code occur at state level, there is insufficient regulatory supervision of the substantiation process to remove all

⁸ See below nn 142–63 and accompanying text.

⁹ John Spink and Douglas C. Moyer, 'Defining the Public Health Threat of Food Fraud' (2011) 76(9) *Journal of Food Science* R157, R158.

¹⁰ See below nn 17–43 and accompanying text.

¹¹ *Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on Nutrition and Health Claims Made on Foods* [2006] OJ L 404/9, art 1(3) ('*Health Claims Regulation (EC) 1924/2006*').

¹² See below nn 39–98 and accompanying text.

¹³ See below nn 101–21 and accompanying text.

¹⁴ *Ibid.*

¹⁵ See below nn 122–42 and accompanying text.

exaggerated and overreaching claims from the marketplace (Section III.C).¹⁶ This is similar to the situation in the US (Section III.B.2). Nor can consumers rely on the federal consumer protection regulator—the Australian Competition and Consumer Commission ('ACCC')—to monitor and supervise health claims on food. The ACCC has had some success in taking enforcement action in relation to false or misleading credence claims on food. However, without powers to enforce the Code, the ACCC is not in a position to proactively monitor food labelling and marketing for false, misleading or non-compliant health claims (discussed in Section II.A.2).¹⁷ This leaves consumers vulnerable to exploitation via 'food fraud'.

II AÇAÍ BERRIES AND ANTI-AGEING HEALTH CLAIMS: A CASE OF 'FOOD FRAUD'

A 'Food Fraud as a Policy Goal for Regulation

1 'Food Fraud'

'Food fraud' is defined by US academics Spink and Moyer and referred to in EU Resolution¹⁸ as 'a collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product for economic gain'.¹⁹ The concept of 'food fraud' complements that of 'food safety' in thinking about the regulatory management of risk and design of food protection control systems.²⁰ Traditional food safety regulation is about the controlling (generally) of *unintentional* acts that risk public health through exposure to microbiological, physical or chemical hazards. By contrast, food fraud control focuses on *intentional* acts that risk public health, through exposure to false or misleading statements about food or food ingredients. The deliberate nature of making false representations in food fraud is 'motivated' by economic gain.²¹

The American Dietetic Association advises that 'food and nutrition misinformation can have harmful effects on the health and economic status of consumers'.²² Much

¹⁶ See below nn 159–63 and accompanying text.

¹⁷ See below nn 31–3 and accompanying text.

¹⁸ European Parliament, *European Parliament resolution of 14 January 2014 on the food crisis, fraud in the food chain and the control thereof (2013/2091(INI))* (14 January 2014) <<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2014-0011&language=EN&ring=A7-2013-0434>>.

¹⁹ Spink and Moyer, above n 9.

²⁰ Ibid R160. The Spink and Moyer 'Food Protection Risk Matrix' incorporates 4 pillars of a food protection system: 'food quality, food safety, food fraud and food defense' within the umbrella concept of 'food security'. The motivations (economic gain or harm such as public health, economic, or terror related harm) are represented in the matrix with reference to whether an action was 'unintentional' or 'intentional'.

²¹ Ibid. Food fraud is further distinguished from 'food defense' in the 'Food Protection Risk Matrix' where although both 'food fraud' and 'food defense' are intentional acts, the motivation for 'food defense' is to cause harms to public health or economics.

²² Keith-Thomas Ayoob, Roberta L. Duyff and Diane Quagliani, 'Position of the American Dietetic Association: Food and Nutrition Misinformation' (2002) 102(2) *Journal of the American Dietetic Association* 260.

writing on food fraud has focused on substitution of certain ingredients in food, but the term 'food fraud' also extends to false or misleading statements intentionally used in the sale or advertising of food for economic gain including false or misleading health claims.

Risks to public health from food fraud have been categorised as 'direct, indirect and technical'.²³ Direct food fraud risk exists where immediate and acute toxicity or illness results from false descriptions of foods or food ingredients following, for example, the substitution of premium ingredients with cheaper, allergenic components.²⁴ Indirect food fraud risks flow from long-term consumption and repeated exposure to an affected food, where discovery of an impact on the public's health may be delayed, for example, the long-term exposure to artificial enhancements added to food to achieve a claimed health effect or food function,²⁵ or a nutritionally defective food missing the claimed beneficial properties of the food,²⁶ or a food with false or misleading health claims specific to the food.²⁷ False descriptions on labels that do not result in a public health hazard (direct or indirect) and concern 'non-material' and non-health related credence attributes (e.g. claims of 'ethical' farming or 'environmental' production practices) are 'technical' food fraud.

This paper is concerned with false or misleading health claims found on 'superfood' products. These create an 'indirect' risk to public health, especially where foods are advertised with 'high level health claims' – claims that mention a 'serious disease or a biomarker to a serious disease'. In Section II.B below we provide a detailed case study of such claims on açai berry superfood products.

²³ See John Spink, 'Defining Food Fraud and the Chemistry of the Crime' in Wayne Ellefson, Lorna Zach and Darryl M. Sullivan (eds), *Improving Import Food Safety* (John Wiley & Sons and the Institute of Food Technologists, 2013) 195, 199-200.

²⁴ For example, the UK has warned consumers of the potentially life threatening activity of using allergenic peanuts and almonds, undeclared, in place of more expensive cumin seeds. See Tom Bawden, *New Food Scandal over Peanuts Is 'More Serious' than the Horsemeat Crisis* (14 February 2015) Independent <<http://www.independent.co.uk/life-style/food-and-drink/news/new-food-scandal-over-peanuts-is-more-serious-than-the-horsemeat-crisis-10045725.html>>.

²⁵ For example, some foods such as coffee, teas and chocolates labelled as natural weight loss products have contained undeclared Schedule IV therapeutic agents withdrawn from the market due to an increase in reported side effects, including blood pressure, cardiac events and strokes. See NSW Food Authority, *Fined for Undeclared Sibutramine Drug in Food* (November 2013) Foodwise Issue 31 <http://www.foodauthority.nsw.gov.au/_Documents/newsletters/foodwise_issue_31_2013.pdf>.

²⁶ See, eg, the prosecution of a drinks company for the false description of a diluted concentrate of deionised apple juice with added preservative, as '99% apple juice, preservative free': *NSW Food Authority (Officer Ian Beer) v P & N Beverages Pty Ltd* (Unreported, Local Court of NSW, Magistrate GJT Hart, 21 July 2008).

²⁷ The most serious of which relate to claims of therapeutic or prophylactic action on physiological conditions and diseases. For example, a 'probiotic yogurt' was sold with claims the food could 'alleviate symptoms of HIV, multiple sclerosis, diabetes and asthma'. See, Robert Burton-Bradley, *Microbioflora Pty Ld Fined for Illegal Health Claims on its Progurt* (19 October 2011), news.com.au <<http://www.news.com.au/finance/small-business/microbioflora-pty-ld-fined-for-illegal-health-claims-on-its-product-progurt/story-f9evb64-1226169820092>>.

2 Food Fraud and Regulation

It is now recognised by the EU and UK that the prevention and control of food fraud is an important policy goal for governments and food regulators.²⁸ In Australia, however, the term food fraud has fallen into abeyance. At common law, misleading statements were previously conceptualised as a form of ‘fraud’ and victims could seek remedies (including damages and injunctions) in tort law (e.g. tort of deceit).²⁹ Yet, even though the term ‘food fraud’ is no longer explicitly used in Australia, state food Acts³⁰ and the Australian Consumer Law³¹ (‘ACL’) prohibit this type of conduct through prohibitions on false representations, misleading or deceptive conduct in the sale and advertising of food specifically, and in the trade of goods, respectively.³² The principles of both regimes broadly align with Spink and Moyer’s definition of food fraud.³³ Similarly, the *Therapeutic Goods Act 1989* (‘TGA’) and its regulations prohibit false representations and

²⁸ See European Parliament, above n 18, where the Resolution includes within its scope ‘Regulation (EC) No 1924/2006 on nutrition and health claims made on foods and Regulation (EU) No 1169/2011 on the provision of food information to consumers’.

²⁹ Common law ‘fraud’ initially required proof that the maker of a statement knew it was untrue. See, eg, *Alati v Kruger* (1955) 94 CLR 216. More recent common law fraud cases reveal a test of whether the maker honestly believed the representation to be true, see *AIC Ltd v ITS Testing Services (UK) Ltd The Kriti Palm* [2006] EWCA Civ 1601, 398. US courts have made it clear that ‘deceptive or misleading commercial speech can still be considered a form of fraud, undue influence, over-reaching, or other vexatious conduct’, *Ohralik v Ohio State Bar Association*, 436 US 447, 462 (1978) cited in Lawrence Gostin, *Public Health Law: Power, Duty, Restraint* (University of California Press, 2000) 160.

³⁰ The *Model Food Act 2000* (Cth) s 1(b) provides that one of the Act’s three objects is ‘to prevent misleading conduct in connection with the sale of food’. The objects and Annex A provisions are adopted in *Food Act 2003* (NSW); *Food Act 1984* (Vic); *Food Act 2008* (WA); *Food Act 2006* (QLD); *Food Act 2001* (SA); *Food Act 2003* (Tas); *Food Act 2001* (ACT); *Food Act 2004* (NT).

³¹ *Competition and Consumer Act 2010* (Cth) sch 2 s 29; *Competition and Consumer Act 2010* (Cth) sch 2 s 18(1) where a breach of the prohibition gives rise to civil remedies. See Chapter 4 of the ACL for criminal liability for certain breaches. Under the ACL, a graduated series of sanctions are provided for misleading or deceptive conduct, as opposed to civil penalties and remedies. The prohibitions are replicated in fair trading legislation in each State and Territory as part of the ACL: *Fair Trading Act 1987* (NSW) s 28; *Fair Trading Act 1989* (Qld) s 16; *Fair Trading Act* (SA) s 14; *Australian Consumer Law (Tasmania) Act 2010* (Tas) s 6; *Fair Trading Act 1999* (Vic) s 9; *Fair Trading Act 2010* (WA) s 11; *Fair Trading (Australian Consumer Law) Act 1992* (ACT) s 7; *Consumer Affairs and Fair Trading Act 1990* (NT) s 27.

³² *Food Act 2003* (NSW) ss 18, 22; *Food Act 2006* (QLD) ss 37, 40; *Food Act 2001* (SA) ss 18, 22; *Food Act 2003* (TAS) ss 18, 22; *Food Act 1984* (VIC) ss 13, 17A; *Food Act 2008* (WA) ss 16, 19; *Food Act 2001* (ACT) ss 15, 24; *Food Act 2004* (NT) ss 17, 21. See, generally, Janine Curll, ‘The Significance of Food Fraud in Australia’ (2015) 43 *Australian Business Law Review* 270, 284–9.

³³ The main difference is that food fraud is deliberate and intentional, but misleading or deceptive conduct under current law does not require proof of an intention to mislead, although intentions are relevant to sentencing. For a discussion on how ‘intention’ has been dealt with by the courts when determining sentencing, see Felicity Lee, ‘False or Misleading Credence Claims: What’s the Harm and Why Should Businesses Care?’ (2014) 22(1) *Australian Journal of Competition and Consumer Law* 5. See also *Australian Competition and Consumer Commission v Homeopathy Plus! Australia Pty Ltd* [2014] FCA 1412 (22 December 2014) [116]–[125], where Perry J provides a useful summary of the relevant principles in determining whether conduct is ‘misleading or deceptive’.

misleading or deceptive conduct in the sale of therapeutic goods that might, in theory, address food fraud. The TGA, however, explicitly excludes 'foods' from the scheme – including the açai superfood products under analysis in this article – and is therefore not relevant.³⁴

In recent years the ACCC has taken a role in enforcement against 'food fraud' by prioritising misleading 'credence claims' on food for enforcement, with a focus on 'consumer value issues'.³⁵ It has taken strong enforcement action in a number of instances of food fraud including misleading uses of the terms 'organic', 'free range' and 'free to roam'.³⁶ The ACCC has also prioritised enforcement against misleading health claims on various non-food products.³⁷ The ACCC is a highly effective enforcement agency and the publication of its enforcement activities may deter some would-be food fraudsters marketing foods with false or misleading claims.³⁸ It is, however, the food regulation system, not the consumer law system or therapeutic goods system, that is most appropriate and best designed to prevent and control food fraud in relation to false or misleading health claims based on overreaching scientific claims found on some 'superfood' and other products.

The ACCC has a very broad remit to take enforcement action in relation to all anti-competitive or unfair trading activity in Australia and must necessarily be selective and reactive in its approach. That is, it takes enforcement action in only a small proportion of cases that it becomes aware of and only does so after the conduct has already occurred and caused harm. By contrast, the bi-national Australian and New Zealand food regulation systems set out standards for food labelling that include scientific proof thresholds for health claims and these are monitored and enforced by state food

³⁴ *Therapeutic Goods Act 1989* (Cth) s 3 provides the definition of therapeutic good, which excludes 'goods (other than goods declared to be therapeutic goods under an order in force under s 7) for which there is a Standard (within the meaning of sub-s 4(1) of the *Food Standards Australia New Zealand Act 1991*) or 'goods (other than goods declared to be therapeutic goods under an order in force under s 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented'.

³⁵ See generally Commissioner Sarah Court, 'Enforcement Priorities at the ACCC' (Speech delivered at the Commonwealth Club of Adelaide, 24 September 2013) <<http://www.accc.gov.au/speech/enforcement-priorities-at-the-accc>>; See also ACCC, 'ACCC Enforcement Guidance – Free Range Hen Egg Claims' (Guidance Document, ACCC, 5 October 2015).

³⁶ See, eg, *Australian Competition and Consumer Commission v Pirovic Enterprises Pty Ltd* [No 2] (2014) ATPR 42–483 (23 September 2014); *Australian Competition and Consumer Commission v RL Adams Pty Ltd* [2015] FCA 1016 (11 September 2015); *Australian Competition and Consumer Commission v Turi Foods Pty Ltd* [No 2] [2012] FCA 19 (23 January 2012); *Australian Competition and Consumer Commission v Turi Foods Pty Ltd* [No 4] [2013] FCA 665 (8 July 2013); *Australian Competition and Consumer Commission v Pepe's Ducks Ltd* [2013] FCA 570 (14 June 2013).

³⁷ See ACCC, *Advertising and Selling Guide* <<https://www.accc.gov.au/publications/advertising-selling/advertising-and-selling-guide/marketing-claims-that-require-extra-care-premium-and-credence-claims/health-claims-and-other-benefits>>.

³⁸ See Christine Parker and Vibeke Lehmann Nielsen, 'The Fels Effect' (2011) 20(1) *Griffith Law Review* 91; Christine Parker and Vibeke Lehmann Nielsen, 'Deterrence and the Impact of Calculative Thinking on Business Compliance with Competition and Consumer Regulation' (2011) 56(2) *The Antitrust Bulletin* 377.

authorities who should be able to take a systematic and preventive approach in preventing potential harm from misleading health claims.³⁹ Since courts are 'ill-equipped' to resolve scientific controversy,⁴⁰ it is preferable for regulations to be prescriptive with respect to required proofs, and courts only called on to adjudicate in cases of breach.

This is precisely what the new *Standard 1.2.7* attempts to do. It requires systematic scientific reviews of the evidence to establish causal links between a food and health effect before a health claim can be made. Thus, it seeks to prevent misleading or deceptive conduct. Indeed, in developing *Standard 1.2.7*, the risk of misleading conduct for economic gain was identified as a significant industry behavioural issue prioritised for control.⁴¹ However, as is argued below (in the second part of this article), although *Standard 1.2.7* sets a high and appropriate standard for scientific evidence for health claims on food, the implementation process it prescribes has significant weaknesses. This is because unlike the EU, where regulator pre-approval is required for all health claims, *Standard 1.2.7* allows food businesses to self-substantiate some food-health relationships. Moreover, a second weakness in the implementation, monitoring and enforcement of *Standard 1.2.7* is that without the requirement for pre-market approvals in Australia, the state food regulators who must implement the Standard may not be sufficiently prioritising and resourcing the monitoring and enforcement of compliance with the new Standard. Indeed, it has already been noted in a review of the regulation system that the risk-based compliance and enforcement strategies of state health and food agencies is likely to direct resources away from monitoring health claim compliance in favour (understandably⁴²) of direct, acute threats to food safety from microbiological, physical or chemical contamination.⁴³ A pre-market authorisation

³⁹ See Curll, above n 32, 288.

⁴⁰ As Hill J noted on behalf of the appellate panel in *Tobacco Institute of Australia Ltd v Australian Federation of Consumer Organisations Inc* (1992) 38 FCR 1, 48, 'At the end of the day, the question of the relationship between environmental tobacco smoke and disease is a matter for scientists trained in the area, it is not a matter for a court of law which is ill-equipped to determine it and to make the skilled judgments upon which such a question depends'.

⁴¹ Food Standards Australia New Zealand ('FSANZ'), *P293 Review Report—Proposal P293*, Review Report (2012) 49.

⁴² FSANZ is obligated to consider the objects of *Food Standards Australia New Zealand 1991* (Cth) s 18(1), which explicitly prioritised in the following descending order: 'the protection of public health and safety', the 'provision of adequate information relating to food to enable consumers to make informed choices' and the 'prevention of misleading or deceptive conduct'.

⁴³ Implementation Subcommittee for Food Regulation ('IFSR'), 'Health claims and Enforcement—How Regulators Will Enforce the Nutrition and Health Claims Standard' (Guidance Document, Department of Health (Cth), 2015) 4. The associated IFSR, 'Bi-National Food Labelling Compliance and Enforcement Strategy' (Guidance Document, Department of Health (Cth), 2015) distinguishes the risk of 'direct, acute, immediate threats to health' from 'indirect, long term impacts on health' and the lowest risk to 'consumer perceptions and ethical views'. Health claim compliance—preventative health/ indirect, long-term impacts on health—is the second priority for the attention of regulators, according to the Strategy. See Australia and New Zealand Ministerial Forum on Food Regulation, 'Overarching Strategic Statement for the Food Regulatory System' (Guidance Document, Department of Health (Cth), 2008).

process for *all* health claims, as in the EU, would ensure a more proactive and effective approach for preventing harm from false and misleading health claims.⁴⁴

The following section illustrates the challenge of combatting misleading health claims on food via a case study of the labelling of açai berry superfood products. We show why açai berries have garnered the attention and imagination of food entrepreneurs. We present an analysis of the available science in support of claims used in the promotion and sale, and argue 'anti-ageing' health claims may be made to induce people to buy a more expensive branded product where less expensive, unbranded fruit and vegetables would have the same health benefits.

B Overreaching Health Claims on Açai Berry Superfood Products

1 Açai Berries as a Superfood

Açai berries come from palm trees that originally grew wild in the Amazon and have been encouraged and tended by local people who have used it as a staple food since before recorded history. The palm on which the berries grow, *Euterpe oleracea*, is considered to be among the most naturally abundant species in 'Amazon estuary floodplains'.⁴⁵ In order to harvest and eat the berries, one must climb the palms, pull down the berries and soak them in water, and then rub the skin and flesh off the large pit (the berry is mainly seed not pulp) by hand or, now, machine.⁴⁶

Originally used by Indigenous Amerindian and later *Caboclo*⁴⁷ groups, açai berries became popular throughout Brazil by the early 1990s due to internal migration of these people to provincial cities from the 1970s.⁴⁸ It was discovered by tourists and exported to Los Angeles in the 1990s, where it became an energy drink.⁴⁹ At first, açai was 'essentially a cult phenomenon, popular mostly among young, male extreme-sport enthusiasts ... skaters, surfers, snowboarders'.⁵⁰ It became more widely popular in the US after it was named as a 'superfood' for anti-ageing in a book and an Oprah Winfrey Show appearance by New York dermatologist and leading 'anti-ageing expert' Dr Nicholas Perricone in 2003 and 2004.⁵¹ By 2013, 'açai-laced products grossed nearly \$200

⁴⁴ See, eg, Deepananda Herath, Spencer Henson and John Cranfield, 'A Note on the Economic Rationale for Regulating Health Claims on Functional Foods and Nutraceuticals: The Case of Canada' (2006) 15 *Health Law Review* 23, 26, which states that proactive regulatory approaches oriented to pre-market approvals provide reliable and verifiable information, thus transforming 'credence attributes to experience or search attributes ... such that there is protection against misleading claims'.

⁴⁵ Michael Heinrich, Tasleem Dhanji and Ivan Casselman, 'Açai (*Euterpe oleracea* Mart.) – A Phytochemical and Pharmacological Assessment of the Species' Health Claims' (2011) 4 *Phytochemistry Letters* 10, 11.

⁴⁶ See John Colapinto, *Strange Fruit: the Rise and Fall of Acai* (30 May 2011) *The New Yorker* <<http://www.newyorker.com/magazine/2011/05/30/strange-fruit-john-colapinto>>.

⁴⁷ An ethnically mixed Amerindian and European/Portuguese settler group.

⁴⁸ See Colapinto, above n 46.

⁴⁹ Heinrich, Dhanji and Casselman, above n 45, 11.

⁵⁰ Colapinto, above n 46.

⁵¹ *Ibid.* The book was Nicolas Perricone, *The Perricone Promise: Look Younger, Live Longer in Three Easy Steps* (Time Warner Book Group, 2004).

million in the United States'.⁵² By this time, açai products had also spread from the US to Australia, especially via beach lifestyle cafes and anti-ageing clinics on Queensland's Gold Coast. Açai berries are now marketed to Australian consumers in frozen pulp form sold as smoothies, as 'bowls' with fruit, yoghurt, coconut milk and granola at cafes and music festivals, and also in powder, pill or capsule form as health foods sometimes labelled 'dietary supplements' in health food and supplement specialty stores.

Anti-ageing entrepreneur Dr Perricone's claim that açai berry products were an 'anti-ageing' 'superfood' appears to have been the defining point in making açai berries popular. Indeed, the claim that a food like the açai berry is a 'superfood' with good health, and specifically anti-ageing, effects is a particularly potent means of marketing; especially in a socio-economic context in which consumers are anxious and aspirational about caring for their own health ('healthism') yet face a multiplicity of conflicting social norms and cues about how and what to eat ('gastro-anomy'). Jessica Loyer has found Australian consumers of superfoods focus on the apparent health benefits of these products, and although they are confused by what is on offer and what benefits these products might provide, they see them as 'extra insurance' or even 'a talismanic object ... providing protection from many of the health threats of the modern world'.⁵³ The next section explains the indirect risk to consumers and public health of these claims in this context.

2 The Potential Harm of Anti-Ageing Health Claims for Consumers and Public Health

The combined contexts of 'healthism' and 'gastro-anomy' make anti-ageing superfood claims particularly attractive. 'Healthism' was first used in 1980 to describe what sociologist Robert Crawford saw as the then prevailing anxiety among the US middle classes about the loss of status arising with increasing unemployment and lower living standards (the 'fear of falling') and a refocusing of attention on the body. It usefully describes the contemporary preoccupation with 'health' as an end in itself.⁵⁴ Indeed under neoliberal policy conditions health care itself has been transformed towards individualised responsibility for one's own health and disease.⁵⁵ Media and advertising have played a key role in exploiting the affluent baby-boomer market, which aspires to

⁵² Tom Philpott, *Are Quinoa, Chia Seeds and Other "Superfoods" a Scam? Sure, Trendy Ingredients Work Like Magic—For Industry's Bottom Line* (2013) Mother Jones <<http://www.motherjones.com/environment/2013/05/are-superfoods-quinoa-chia-goji-good-for-you>>.

⁵³ Jessica Loyer, *Smoothies as Talismans: the Allure of Superfoods and the Dangers of Nutritional Primitivism* (21 July 2016) The Conversation <<https://theconversation.com/smoothies-as-talismans-the-allure-of-superfoods-and-the-dangers-of-nutritional-primitivism-62424>>.

⁵⁴ Robert Crawford, 'Healthism and the Medicalization of Everyday Life' (1980) 10(3) *International Journal of Health Services* 365.

⁵⁵ Toni Calasanti, 'Bodacious Berry, Potency Wood and the Aging Monster: Gender and Age Relations in Anti-Aging Ads' (2007) 86(1) *Social Forces* 335.

health, beauty and never ending youth.⁵⁶ Anti-ageing marketing claims in particular draw on this discourse of 'healthism'.⁵⁷

Anti-ageing superfood claims particularly appeal to consumers in a social and cultural context of 'gastro-anomy'.⁵⁸ Food anthropologist and sociologist Claude Fischler coined the term 'gastro-anomy' to refer to the increasing sociocultural separation between food production and consumption resulting in consumers who do not know, who may be unaware or may simply not wish to follow traditional cultural and religious norms.⁵⁹ Fischler argues that the creation and proliferation of diverse food choices within the contemporary global market tend to confuse rather than 'empower' the consumer,⁶⁰ leaving them in a state of 'gastro-anomy' or 'eating normlessness'.⁶¹ However, it might be more accurate to say that rather than being 'normless', eating is these days subject to many conflicting and competing normative claims so as to present consumers with a constant series of choices. The expansion of choice provides much opportunity for experiencing a variety of food and healthy eating options but it can also become a source of 'anguish and obsession, anxiety and suspicion'.⁶² For food businesses, it is an opportunity to exploit consumers who are confused and/or anxious.

Warde suggests that a range of social mechanisms seek to help consumers choose what and when to eat in a context of expanded choice and competing norms.⁶³ These mechanisms include the provision of advice by nutritionists, official medicine, alternative medicine, food producers and advertising.⁶⁴ Schneider and Davis' analysis of the content of women's magazines suggests that food advertising offers up-branded products as solutions to the 'problem' of too much choice.⁶⁵ This also creates opportunities for the exploitation of consumers and the dilution of public health messages via marketing claims made for economic gain. Thus, Schneider and Davis warn that it is important to examine in whose interests and to what end recommendations are made in food advertising, since these influence and govern consumers' sense of what they should eat.⁶⁶ The labelling of a food (in this case açai

⁵⁶ Angela McRobbie, *The Aftermath of Feminism: Gender, Culture and Social Change* (Sage Publishing, 2009); MacGregor, Petersen and Parker, above n 1; Julie Guthmann, *Weighing In: Obesity, Food Justice and the Limits of Capitalism* (University of California Press, 2011) 52–65.

⁵⁷ Barbara Cardona, "'Anti-Aging Medicine' and the Cultural Context of Aging in Australia' (2007) 1114(1) *Annals of the New York Academy of Sciences* 216.

⁵⁸ Claude Fischler, 'Food, Self and Identity' (1988) 27(2) *Social Science Information* 275, 290–1.

⁵⁹ See also Harvey Levenstein, *Fear of Food: A History of Why We Worry about What We Eat* (University of Chicago Press, 2012); Alan Warde, *Consumption, Food and Taste* (Sage Publications, 1997) 55, arguing that 'the unprecedented range of products that are made available for sale ... poses a perpetual problem of selection for consumers'.

⁶⁰ Jane Dixon and Catherine Banwell, 'Re-embedding Trust: Unravelling the Construction of Modern Diets' (2004) 14(2) *Critical Public Health* 117.

⁶¹ Fischler, above n 58.

⁶² Claude Fischler, 'Food Habits, Social Change and the Nature/Culture Dilemma' (1980) 19 *Social Science Information* 937.

⁶³ Warde, above n 59, 31; following Zygmunt Bauman, *Freedom* (Open University Press, 1988).

⁶⁴ *Ibid.*

⁶⁵ Tanja Schneider and Teresa Davis, 'Advertising Food in Australia: Between Antinomies and Gastro-anomy' (2010) 13(1) *Consumption, Markets and Culture* 31.

⁶⁶ *Ibid.* 32 citing Dixon and Banwell, above n 60.

berry products) as a 'superfood' with health, and specifically anti-ageing, claims may be a particularly potent means of marketing a product to consumers desirous and even anxious about caring for their own health, but who face conflicting social norms and cues about how and what to eat. The involvement of food producers who export, process, brand and retail these products, at a high price, demands critical examination and regulatory attention to ensure that consumers are not exploited and that public health messages (such as the value of eating a variety of fresh fruit and vegetables) are not overwhelmed by private marketing messages (such as the value of branded and often processed superfoods). In this context, a strategic, proactive approach to preventing and controlling food fraud is particularly important.

3 Analysis of Anti-Ageing Health Claims on Açai Products

In order to conduct a comprehensive review of health claims made on açai product labelling, we identified all the açai berry products available in Australia at a point in time by searching publicly available government and private databases before conducting a Google search.⁶⁷ Twenty-nine companies/businesses⁶⁸ were identified selling between them 38 açai products. Freeze dried powder was the most common form in which açai was sold, with pills or capsules and drinks and juices also common (see Table 1).

Upon identifying each açai product advertised for sale in Australia, all words and phrases used to describe the composition of the product, processing, dose instructions, certification and claimed health benefits on the label and in descriptions were recorded through a combination of capture of online advertising and retail site visits.⁶⁹ Table 1

⁶⁷ In Australia, açai berry products are advertised and sold online, in health food stores, pharmacies, supermarkets, cafes and gyms. All trademarks registered in Australia with the terms 'açai' or 'amazon' found on IP Australia were recorded and the Australian trademarked websites accessed. Details of açai products advertised for sale on the trademark related websites were compiled. The 'açai' term was applied in the search of the ASIC business and company names database. Entities with the word 'açai' in the name not initially identified through the use of a registered trademark were selected and searches of websites were conducted to collate details on the açai products for sale. The Australian Certified Organics ('ACO') database was accessed using the keyword 'açai' and a search was conducted. Company websites identified through ACO were searched and the details of further açai products available for sale compiled. Google searches using the terms 'açai' and 'buy' identified additional 'açai' products available for sale in Australia. Products were also identified in searches of Australian sellers on ebay.com.au. Those products not previously identified were added to the Excel spread sheet compilation.

⁶⁸ Including one specialist café.

⁶⁹ Images of packaging labels for each product available for review online were observed and information recorded. A total of five (5) Sydney located health food stores and pharmacies were visited in a search for the pills, juices and powdered açai products identified online in an effort to record any omitted information contained on labels at retail. Not all products were observed on the shelves of the visited retail stores. For the products located, photographs were taken and information presented on labels recorded with the compiled information. One cafe and one juice bar found to be selling the two frozen pulp products, respectively, was visited in Sydney and the product information detailed on the labels were recorded along with additional information provided in advertising pamphlets at point of sale. All information provided in the advertising (online content, label information and/or

summarises the form of products found, where they were sold, the dose or use encouraged and the type of claims made on the labels in relation to health, anti-ageing, antioxidants and the 'exotic back story' of origins in the Amazon.

In the following sections, we analyse in more detail the health claims made on the labels and in online advertising, their interaction with anti-oxidant claims and the exotic back story of origins in the Amazon, and we critically evaluate how well-supported they are. We argue that no unique evidence supports the promotion of açai berry products as a superfood over other nutrient dense foods and preliminary research findings of relatively unknown properties of food are represented as statements of fact in the context of a commercial transaction. We conclude (in Section II.B.6) that some of these claims or the manner in which they are enlisted to influence purchasing choices may amount to a type of food fraud.⁷⁰

4 Açai Berry Product Labelling: Unsubstantiated Anti-Ageing Health Claims Likely to Mislead or Deceive Consumers

As Table 1 shows, many Australian açai products claim to have particular, sometimes unique, health-giving and even 'anti-ageing' properties. The anti-ageing claims are grounded in the generally accepted but not thoroughly understood free radical theory of ageing.⁷¹ According to the theory, free radicals⁷² cause damage to human cellular components, contributing to life-limiting diseases such as cancer, heart disease and immune system decline. 'Anti-oxidants' are theorised to protect cells from this damage.⁷³ Scientific agreement exists for well-characterised vitamins and minerals such as beta-carotene, lycopene, vitamins A, C and E; substances found in a wide range of ordinary fruit and vegetables not marketed as 'superfoods'.⁷⁴

point-of-sale pamphlets) of the identified products was compiled into the Excel spread sheet to facilitate the analysis.

⁷⁰ See below nn 95–8 and accompanying text.

⁷¹ Denham Harman, 'Aging: A Theory Based on Free Radical and Radiation Chemistry' (1956) 11 *Journal of Gerontology* 298. See also Denham Harman, 'The Aging Process' (1981) 78(11) *Proceedings of the National Academy of Science* 7124. This theory is supported by mammalian studies of transgenic mice. See also, Samuel Schriener, Nancy Linford, George Martin, Piper Treuting, Charles Ogburn, Mary Emond, Pinar Coskun, Warren Ladiges, Normal Wolf, Holly Van Remmen, Douglas Wallace and Peter Rabinovitch, 'Extension of Murine Life Span by Overexpression of Catalase Targeted to Mitochondria' (2005) 308 *Science* 1909.

⁷² Ibid. Technically known as 'reactive oxygen species'.

⁷³ The US National Cancer Institute at the National Institute of Health defines antioxidants as 'chemicals that interact with and neutralize free radicals' (unstable molecules made by the process of oxidation during normal metabolism). Free radicals may play a part in cancer, heart disease, stroke, and other diseases of aging. Antioxidants include beta-carotene, lycopene, vitamins A, C, and E, and other natural and manufactured substances'. National Cancer Institute, *Antioxidants and Cancer Prevention* (16 January 2014) <<https://www.cancer.gov/about-cancer/causes-prevention/risk/diet/antioxidants-fact-sheet>>.

⁷⁴ Bruce Ames, Mark Shigenaga and Tory Hagen, 'Oxidants, Antioxidants, and the Degenerative Diseases of Aging' (1993) 90(17) *Proceedings of the National Academy of Sciences of the United States of America* 7915, which promoted an increase in the consumption of fruits and vegetables, arguing '[o]xidant by-products of normal metabolism cause extensive damage to DNA, protein and lipid ... this damage (the same as that produced by radiation)

TABLE 1: SUMMARY OF THE FORMS OF ACAI BERRY PRODUCT SOLD WITH EXAMPLES OF DOSE AND TOTAL NUMBER MAKING VARIOUS HEALTH AND SCIENTIFIC CLAIMS TOTALS

FORM OF ACAI PRODUCT	NUMBER OF PRODUCTS (n=38)	DOSE/USE INFORMATION (examples)	LABEL CLAIMS				
			Anti-ageing	Antioxidants	Phytochemicals	'serious disease'	Exotic Backstory
Freeze dried powder	14	'2 x 5gram heaped teaspoons daily'; 'mix 1 tablespoon with juices, tea, yogurt, (soy, rice, almond) milk or sprinkle over fruit salads, ice cream or porridge'; 'mix 1-2 teaspoons (5g) daily into water, juice, smoothies, yoghurt, cereal or other foods you enjoy daily'; 'add 1 to 3 tablespoons of Acai to your favourite juice, smoothie or cereal once or twice a day'; 'add to yoghurt, smoothies, ice cream, fruit juice, water, milkshakes, muesli or even margaritas!'	7/14	14/14	10/14	4/14	7/14
Pills/capsule	8	'take six daily'; 'take 2 capsules daily'; 'take 1-2 capsules per day, or as required'; 'take 1-2 gelcaps with meals'; 'can consume 1-4 capsules per day for the entire family'	2/8	6/8	2/8	3/8	3/8
Fruit juice/drink	8	'Drink 30ml to 6ml twice daily with meals'; 'add 1 part acai juice (30ml-50ml) to five parts water (150ml-250ml) or other juice. Consume throughout the day as desired'; 'dilute 1 part (30-50ml) with 5 parts (150-250ml) water'	1/8	7/8	2/8	2/8	6/8
Frozen pulp	3	'blend two packs in smoothie daily'	1/3	3/3	1/3	2/3	2/3
Tea	2	'for maximal results we suggest using Acai tea in conjunction with a detox (14-28 days). Consume the tea in the middle of the day'	1/2	2/2	0/2	0/2	1/2
Coffee	1	Coffee sachets with dried acai	0/1	0/1	0/1	0/1	0/1
Sports gel	1	Gel sachets	0/1	0/1	0/1	0/1	0/1
Alcohol	1	Standard drink serving	0/1	0/1	0/1	0/1	0/1
Total	38		12/38	32/38	16/38	11/38	20/38

Of the 38 açai products identified, 32 refer to ‘antioxidants’ and their health-giving properties including all of the powders (14/14), pulps (3/3) and teas (2/2), two thirds (6/8) of the pills, and 7 out of 8 of the juices (see Table 1).⁷⁵ Eleven of the products explicitly link this to ‘anti-ageing’.⁷⁶ Similarly, eleven products (4/14 powders; 3/8 pills; 2/8 drinks; and 2/3 pulps) mention a ‘serious disease’ in their labelling or advertising and thus make restricted ‘high level health claims’ under *Standard 1.2.7*.⁷⁷

The claims on these products attribute to açai berries some generally well-accepted health benefits that come from eating any of a whole range of fresh fruit and vegetables due to the antioxidant capacity of vitamins and/or other components in these foods. ‘Superfood’ claims, however, seek to distinguish some fruit and vegetables, such as açai, from other ‘normal’, unbranded fruit and vegetables on the basis that a particular set of bioactive molecules (or ‘phytochemicals’) in the food are especially potent antioxidants.⁷⁸ Scientific research about the impact of particular phytochemicals on health is, however, indirect, relatively preliminary and by no means definitive.⁷⁹ There are no studies establishing a causal relationship between particular phytochemicals and

is a major contributor to aging and to degenerative diseases of aging such as cancer, cardiovascular disease, immune-system decline, brain dysfunction, and cataracts. Antioxidant defenses against this damage include ascorbate, tocopherol, and carotenoids and are one source of tocopherol. Low dietary intake of fruits and vegetables doubles the risk of most types of cancer as compared to high intake and also markedly increases the risk of heart disease and cataracts. Since only 9% of Americans eat the recommended five servings of fruits and vegetables per day, the opportunity for improving health by improving diet is great.’

75 In an example from our study, Natures Goodness® Açai Power™ claims ‘Açai Power™ is a potent source of antioxidants—substances which protect the body from the harmful effects of free radicals and oxidative damage ...’.

76 In an example from our study, Amazon Power® Pure Açai pulp claims ‘Helps you look younger and live longer! With the highest concentration of antioxidants of any berry on the plant, açai helps reduce the signs of ageing and stress’.

77 In an example from our study, Bioglan® Açai + Berry powder claims ‘What: Açai Berry. Why: Originating in the Amazon these berries are packed full of nutrients, particularly antioxidants. ... Antioxidants protect our body from damaging effects of inflammation, an aggravating factor in heart disease.’ The regulatory regime for high level health claims is discussed below nn 101–21 and accompanying text.

78 Sandhya Khurana, Krishan Venkataraman, Amanda Hollingsworth, Matthew Piche and T.C. Tai, ‘Polyphenols: Benefits to the Cardiovascular System in Health and in Ageing’ (2013) 5(10) *Nutrients* 3779, 3797–8. Specifically, it is the ‘anthocyanins’ (a particular type of polyphenol) that are highly concentrated in the açai berry that is claimed to be of particular benefit. These anthocyanins are associated with the dark purple pigmentation in açai berries and are also found in cranberries, raspberries, blueberries, red grapes, red cabbage, eggplant skin and plums. See Juan Carlos Espín, Maria García-Conesa and Francisco Tomás-Barberán, ‘Nutraceuticals: Facts and Fiction’ (2007) 68(22) *Phytochemistry* 2986, 2987. See also, Maria Elisa Schreckinger, Jennifer Lotton, Mary Ann Lila and Elvira Gonzalez de Mejia, ‘Berries from South America: A Comprehensive Review on Chemistry, Health Potential and Commercialization’ (2010) 13(2) *Journal of Medicinal Food* 233.

79 Lunn, above n 2, 171 points out that epidemiological studies confirm segments of the population who consume larger amounts of cruciferous vegetables (e.g. broccoli), and thus glucosinolates (which break down to form isothiocyanates to induce potentially anti-carcinogenic defence mechanisms), are afforded some degree of disease protection.

human health and taking into account the form of the food, process of manufacture, bioavailability and dose.⁸⁰

Superfood marketing platforms use selective scientific information from preliminary laboratory-based research to create overreaching health claims that potentially mislead or deceive consumers. One example is the way marketing claims appeal to the ORAC (oxygen radical absorbance capacity) scale to suggest that açai berries (and other superfoods) are uniquely health-giving and anti-ageing.⁸¹ Indeed, in 2012 the US Department of Agriculture (which regulates food in the US) withdrew an ORAC database from its Nutrient Data Laboratory website in 2012 with the explanation that it was 'routinely misused' by food businesses and that 'there is no evidence that the beneficial effects of polyphenol-rich foods can be attributed to the antioxidant properties'.⁸²

Published research demonstrates that açai *may* have anti-cancer activity and *may* protect the heart due to its antioxidant profile,⁸³ but evidence from human clinical trials undertaken to date do not provide sufficient evidence to assert the health claims as fact.⁸⁴ Direct scientific evidence does show that a diet rich in vegetables and fruits

⁸⁰ See Laura Rubio, Alba Macia, and Maria-Jose Motilva, 'Impact of Various Factors on Pharmacokinetics of Bioactive Polyphenols: An Overview' (2014) 15(1) *Current Drug Metabolism* 62. See also Pedro Mena, Nuria Martis, Cristina Garcia-Viguera, 'Varietal Blends as a Way of Optimizing and Preserving the Anthocyanin Content of Pomegranate (*Punica granatum* L.) juices' (2014) 62(29) *Journal of Agricultural and Food Chemistry* 6936. For a discussion on the variability of measured antioxidant capacities and the effects of simulated digestion of dietary supplements *in vitro*, see Susanne Henning, Yanjun Zhang, Victoria Rontoyanni, Jianjun Huang, Ru-Po Less, Amy Trang, Gloria Nuernberger and David Heber, 'Variability in the Antioxidant Activity of Dietary Supplements from Pomegranate, Milk Thistle, Green Tea, Grape Seed, Goji, and Açai Effects on *in vitro* Digestion' (2014) 62(19) *Journal of Agricultural and Food Chemistry* 4313. Further note that because laboratory-measured activity *in vitro* does not reflect the activity in the human body, such measurements 'cannot be an indicator for its 'goodness' to the human body', Espin, García-Conesa and Tomás-Barberán, above n 78.

⁸¹ In an example from our study, RioLife® 100% Organic Freeze-dried Açai powder claims 'When measuring a food's antioxidant potential, scientists use a scale called ORAC (oxygen radical absorbance capacity). Using the ORAC scale, açai berries are one of the most potent sources of antioxidants you'll ever find. In fact, while fresh fruit or veggies provide you with 890 to 2500 ORAC units per serving, just one 5 gram serving of 100% Certified Organic Açai powder packs in a whopping 4,695 ORAC units ... so think of the antioxidant capacity of açai berries like this: one 5 gram tablespoon of 100% Certified Organic Açai powder contains about the same amount of antioxidants as 120 blueberries.'

⁸² United States Department of Agriculture Agricultural Research Service, *Frequently Asked Questions: What is the Status of the USDA Database for the ORAC of Selected Foods?* (15 August 2016) United States Department of Agriculture <<http://www.ars.usda.gov/Main/docs.htm?docid=6233>>.

⁸³ Heinrich, Dhanji and Casselman, above n 45.

⁸⁴ Thea Magrone, Fatima de Heredia, Emilio Jirillo, Giuseppa Morabito, Ascension Marcos and Mauro Serafini, 'Functional Foods and Nutraceuticals as Therapeutic Tools for the Treatment of Diet-Related Diseases' (2013) 91 *Canadian Journal of Physiology and Pharmacology* 387, 393. The authors state that 'further and more homogenous investigations in humans are needed to identify the bioactive ingredients in food involved in the modulation of low-grade inflammation in diet-related disease'. The US National Centre for Complementary and

generally has a protective effect on cancer,⁸⁵ and studies reveal an inverse association with diseases of the cardiovascular system.⁸⁶ However, the causal mechanisms for the food and health relationships remain elusive and the subject of much study. There is no conclusive scientific evidence for any unique health and anti-ageing claims in the sale of açai berry or other superfood products over other nutrient dense foods.

5 Açai Berry Product Labelling: Using an Exotic Backstory to Create a 'Superfood'

Even fruits with measured polyphenol profiles comparable to açai berries,⁸⁷ such as blueberries, blackberries, blackcurrants, strawberries and cranberries, artichokes, prunes, black grapes, and red onions, have not achieved the same status as undisputed 'superfoods' as açai berry products and other exotic, imported foods like goji berries and chia. Critical US news magazine *Mother Jones* reported that in 2013 blueberries only generated US\$3.5 million, 'less than 2 percent of açai based products', and suggested that it was the 'exotic back story' that helped turn açai berries into 'superfoods'.⁸⁸ The Australian açai products studied suggest this may be so. Just over half (20 out of 38) of the products refer to the exotic origins of the açai berry (see Table 1).⁸⁹

Labelling implies that it is the mystical origins in the Amazon jungle itself that contributes to the superior properties of the açai berry. One product refers to '[o]ver 50 essential nutrients many unique to the Amazon soil' (Amazonia®, frozen smoothie packs). Another story puts together the scientific and naturalistic stories to show how buying an expensive⁹⁰ supplement powder can help the consumer 'unlock the energy of the Amazon'.⁹¹

Alternative Medicine advises there is a lack of 'definitive scientific evidence based on studies in humans to support the use of açai berry for any health-related purpose': National Centre for Complementary and Integrative Health, *Açai* (12 April 2016) National Institutes of Health <<http://nccam.nih.gov/health/açai/ataglance.htm>>.

⁸⁵ Christina Nagle, Louise Wilson, Maria Celia Hughes, Torukiri Ibiebele, Kyoko Miura, Christopher Bain, David Whiteman and Penelope Webb, 'Cancers in Australia in 2010 Attributable to Inadequate Consumption of Fruit, Non-Starchy Vegetables and Dietary Fibre' (2015) 39 *Australian and New Zealand Journal of Public Health* 422. The review implies that 'increasing the proportion of Australians who consume the recommended intake of fruit, vegetables and fibre could prevent up to 4% of all cancers'.

⁸⁶ Lus Dauchet, Phillippe Amouyel, Serge Hercberg and Jean Dallongeville, 'Fruit and Vegetable Consumption and Risk of Coronary Heart Disease: A Meta-Analysis of Cohort Studies' (2006) 136 *Journal of Nutrition* 2588.

⁸⁷ See Mario Perez-Jimenez, Vos Neveu, Augustin Scalbert, 'Identification of the 100 Richest Dietary Sources of Polyphenols: an Application of the Phenol-Explorer Database' (2010) 64 *European Journal of Clinical Nutrition* S112, S114.

⁸⁸ Philpott, above n 52.

⁸⁹ For example, an açai berry fruit juice drink in Woolworths refers to 'The açai berry from the Brazilian rainforest' as 'the tree of life'. Another line of açai juice products from MonaVie™ suggests that, '[f]or countless centuries, the people of the Amazon have revered this unique fruit for its nutritional content and prized it as a source of health and vitality'.

⁹⁰ The recommended retail price for 50g of açai berry powder purchased online is in the range of \$15 to \$20, while a kilo of powder retails at around \$250.

⁹¹ In an example from our study, Bioglan® Açai + Berry Powder claims '[n]ow you can unlock the energy of the Amazon & better health every day. Açai + Berry powder delivers a powerful dose of supercharged berries to revitalize your body. A combination of berries including the

As we saw in Section II.B.2 above, the contemporary high-income consumer is looking for a combination of self-care and social meaning in the food they buy. The labelling of açai berries and other superfoods delivers this in abundance with its combination of impressive-sounding scientific claims about the health benefits of micro nutrients on the one hand, and the naturalism and mysticism of claims about the history of the açai berry on the other. An in-depth *The New Yorker* article about the açai berry phenomenon quotes anthropologist Jane Fajans' observation that this exotic backstory means that açai berry could become

a kind of balm for millennial anxieties ... a miracle cure for, among other things, obesity, attention-deficit disorder, autism, arthritis, Alzheimer's disease, and erectile dysfunction ... There are all these claims ... that it takes away the toxicity of living in the First World and transports you back to the healthy, natural world of the rainforest.⁹²

The exotic claims about the origins of the açai berry may amount to mere 'puffs',⁹³ yet they add potency to overreaching scientific claims. A representation may indeed be 'misleading' although not strictly a 'false representation', the prohibitions extending to advertising puffery when supported by the facts of the case.⁹⁴

6 Summary: Açai Berry Superfood Anti-Ageing Claims as 'Food Fraud'

Our case study of açai berry labelling and marketing claims suggests that a category of (exotic) fresh fruit – the açai berry – has been branded, marketed and 're-classified' as a 'superfood' with anti-ageing properties.⁹⁵ This is done by distinguishing açai berries

superfruits Açai, Goji and Pomegranate plus Blueberry, it delivers vital nutrients, minerals and loads of antioxidants in their natural form for purer health ... This antioxidant rich supplement helps protect your cells from the damaging effects of free radicals. The more colour the better! These deep blue, purple and red berries are particularly rich in antioxidants, anthocyanins and polyphenols turning them from berries to SUPERBERRIES!.

⁹² Colapinto, above n 46; see also Loyer, above n 53.

⁹³ Puffery in advertising is the use of words or statements not intended to be statements of fact and therefore not a 'representation'. See, for example, *Magennis v Fallon* (1828) LR 2 Ir 167; 2 Mol 561, 588. The legislative prohibitions on misleading or deceptive conduct make no distinction between representations and puffery; the courts decide on the basis of the facts.

⁹⁴ For example, half-truths may be misleading due to the erroneous conclusion permitted to be drawn from insufficient information: see, eg, *Australian Competition and Consumer Commission v Coles Supermarkets Australia Pty Ltd* [2014] FCA 634 (18 June 2014) ('Baked Today, Sold Today', 'freshly baked', 'baked fresh' claims on imported, par baked bread finished in store ovens). Allsop CJ cites *Fraser v NRMA Holdings Ltd* (1994) 124 ALR 548, 563. At [47], Allsop CJ noted, 'Where advertising material uses simple phrases and words evoking attractive notions, but without necessarily precise meaning, ambiguity or reasonably available different meanings may well arise. Context and the "dominant message" will be important. If one or more of the reasonably available different meanings is misleading, the conduct may well be misleading or deceptive, or false and misleading'. Further, the Courts consider that 'literal truths' must not create false impressions: see *Hornsby Building Information Centre Pty Ltd v Sydney Building Information Centre Ltd* (1978) 140 CLR 216, 227. However, the protections do not extend to obvious exaggerations or conduct that is merely confusing: see *Ballantyne v Raphael* (1889) 15 VLR 538, 547; 11 ALT 34.

⁹⁵ Anne Cronin makes the point that commodities, such as the açai berry in this survey, are ordered and re-ordered by marketing, converting conventional food to a new status: Anne Cronin, 'Regimes of Mediation: Advertising Practitioners as Cultural Intermediaries' (2004)

and other ‘superfoods’ from ordinary foods using ‘literal truths but false messages’⁹⁶ extrapolated out of the laboratory context to be miscommunicated to the public as scientific fact for profit. The claims observed have not been scientifically proven to a satisfactory evidential threshold that justifies the consumption of processed, branded fruit over a variety of less expensive, more available fresh, unprocessed, fruit and vegetables. Indeed, the use of ‘science’, and the range of scientific terms (antioxidants, phytochemicals, free radicals, polyphenols, anthocyanins etc.) in the absence of validated methods to quantify these claimed food constituents, may work to confuse and mislead the consumer.⁹⁷ The evidence from our survey reveals a manipulation of scientific information from an isolated context (e.g. *in vitro* molecular based assay studies) to create an overall impression that is arguably aimed at encouraging consumers to spend more money than is necessary or scientifically justified on foods that are often presented as health ‘supplements’ but are not regulated by the TGA as therapeutic goods.⁹⁸

The promotion of food with health claims or other information that has not been substantiated to the standard of proof required by law is a deliberate and intentional act amounting to food fraud. The activity requires proactive and effective regulatory measures to reduce the risk of harm. This intentional conduct may lead aspirational or anxious consumers, confused by competing claims, into error about consumption choices with an ultimate impact on their health and in some cases even their financial status.

III A PROACTIVE REGULATORY SYSTEM TO CONTROL AND PREVENT FOOD FRAUD?

The health claims on açai product labelling discussed above have been developed under the previous health claims regulation regime, which ended in January 2016. In this second part of the paper we consider whether new *Standard 1.2.7* is likely to address food fraud in the marketing of superfoods, such as açai berries. We contrast the likely operation of *Standard 1.2.7* with the way the EU regulatory system has operated to—in effect—prohibit general well-being claims, such as ‘superfood’, if not accompanied by an evidence-based health claim that has been pre-approved by the regulator.⁹⁹

FSANZ indicates the introduction of *Standard 1.2.7* should work to ‘mitigate’ the likelihood of consumers being misled or deceived by nutrition content and health claims.¹⁰⁰ We argue that the new standard does address food fraud via misleading

7(4) *Consumption, Markets and Culture* 349, 364–5, cited in Schneider and Davis, above n 65, 33.

⁹⁶ Terminology coined in Victor Herbert, ‘Health Claims in Food Labelling and Advertising: Literal Truths but False Messages; Deceptions by Omission of Adverse Facts’ (1987) 22(3) *Nutrition Today* 25.

⁹⁷ Joint FAO/WHO Codex Alimentarius Commission, *Guidelines for Use of Nutrition and Health Claims: CAC/GL 23–1997*, 8.1.3.

⁹⁸ *Therapeutic Goods Act 1989* (Cth) s 3. See above n 34 and accompanying text.

⁹⁹ *Regulation (EC) 1924/2006 of the European Parliament and of the Council of 20 December 2006 on Nutrition and Health Claims Made on Foods* [2006] OJ L 404/9, art 1.3 (‘*Health Claims Regulation (EC) 1924/2006*’).

¹⁰⁰ Food Standards Australia New Zealand, ‘P293 Review Report—Nutrition, Health and Related claims’ (Review Report, FSANZ, 2012) 49.

health claims in its substance but the system for implementation and monitoring of the new standard is not likely to be as effective as Health Claims Regulation (EC) 1924/2006 in the EU. Indeed, Australia may experience compliance and enforcement challenges associated with the self-regulatory pathway of claim substantiation, as has been observed in the US system. Most significantly, if compliance with *Standard 1.2.7* is not proactively and consistently monitored to ensure its enforcement by all the food regulators in Australian and New Zealand jurisdictions, self-substantiated health claims (general disease or serious disease claims) may remain in the market in breach of the important requirement of proof. This may create an indirect risk to public health by misleading consumers and thereby detrimentally impacting their capacity to make informed and accurate choices.

A *Standard 1.2.7*: A New Approach to Regulating Health Claims on Food Labelling in Australia

The full implementation of *Standard 1.2.7* represents a watershed moment for Australia and New Zealand in the history of health claim policy and the regulation of food. The control of the sale and advertising of products defined as complementary medicines remains the distinct responsibility of the TGA. In addition to setting out conditions and permissions for the labelling of foods with nutrition content claims, it prescribes the process to achieve an acceptable threshold level of scientific evidence of the relationship between a food and health effect (a critical scientific and regulatory concept known as the 'food health relationship') before a food business can make health claims.¹⁰¹ It sets out two pathways for substantiating food health relationships: regulator pre-approval is required for high level health claims¹⁰² ('HLHCs'), but either regulator pre-approval or, controversially, industry-based self-substantiation¹⁰³ is allowed for general level health claims ('GLHCs').¹⁰⁴ *Standard 1.2.7* also sets out a 'healthy'¹⁰⁵ food measurement indicator the Nutrient Profiling Scoring Criteria ('NPSC'), an issue that will not be discussed in this paper.¹⁰⁶ Table 2 summarises types of health claims, as defined in Australia, the US and the EU.

The new system differs from Australia's previous regime (Transitional Standard 1.1A.2 of the Code), which, until the beginning of 2016, at least theoretically prohibited the use of 'therapeutic or prophylactic action' claims, statements that could be interpreted as 'advice of a medical nature', the use of the 'name of, or reference to, any disease or physiological condition', and the word 'health' in connection with the name of the food, in the sale of food.¹⁰⁷ Research shows that the online marketplace and print

¹⁰¹ *Standard 1.2.7* s 2 provides that 'health claim means a claim which states, suggests or implies that a food or property of food has, or may have, a health effect'. *Standard 1.2.7* s 20 provides how health claims are to be made.

¹⁰² *Ibid.* '[H]igh level health claim means a health claim that refers to a serious disease or a biomarker of a serious disease'.

¹⁰³ *Ibid* s 18(3)(b) where sch 6 prescribes the elements of a systematic review.

¹⁰⁴ *Ibid.* A 'general level health claim means a health claim that is not a high level health claim'.

¹⁰⁵ *Ibid* s 18(1)(a) provides that to carry a health claim, foods must meet a value-based scheme critical of energy, saturated fatty acids, sugars and sodium levels.

¹⁰⁶ See *Standard 1.2.7* sch 5. For critical discussion see Gyorgy Scrinis and Christine Parker, 'Front-of-pack Labelling and the Politics of Nutritional Nudges' (2016) 38(3) *Law & Policy* 234.

¹⁰⁷ *The Code*, Transitional Standard on Health Claims Standard 1.1A.2 s 3.

advertisements have at times been littered with misleading or deceptive, false and/or unsubstantiated claims,¹⁰⁸ and prohibited high-level disease risk reduction or therapeutic claims.¹⁰⁹ State regulators reportedly found the old standard 'difficult' to prosecute due to 'ambiguities' and were therefore 'reluctant to commit scarce resources towards [enforcement] action'.¹¹⁰ An industry-administered voluntary Code of Practice on Nutrient Claims in Food Labels and in Advertisements¹¹¹ ('CoPoNC') complemented the legal requirements with guidance on the making of nutrient content claims but was unenforceable by regulators. The self-regulatory approach failed to be effective, as demonstrated by non-compliance in the marketplace and the associated failure by the administering Australian Food and Grocery Council to report on enforcement activities.

The new *Standard 1.2.7* reflects international guidance that food labelling should be proactively regulated so that food businesses may be allowed to make health claims to consumers, but only where those health claims have been substantiated to a legal standard of scientific certainty.¹¹² However, as identified above, *Standard 1.2.7* departs from the apparent international consensus that a regulator is best placed to review all types of disease related claims.¹¹³ In Australia and New Zealand, food businesses can

¹⁰⁸ See, eg, Peter Williams, Health Yeatman, Leisa Ridges, Annalie Houston, Jillian Rafferty, Anna Roesler, Megan Sobierajski and Bronwyn Spratt, 'Nutrition Function, Health and Related Claims on Packaged Australian Food Products – Prevalence and Compliance with Regulations' (2005) 15(1) *Asia Pacific Journal of Clinical Nutrition* 10; Peter Williams, Heather Yeatman, Sally Zakrzewski, Brooke Aboozaid, Simon Henshaw, Kendall Ingram, Alex Rankine and Sara Waleott, 'Nutrition and Related Claims Used on Packaged Australian Foods – Implications for Regulation' (2003) 12(2) *Asia Pacific Journal of Clinical Nutrition* 138, where 12.9% of 6662 products were non-complaint with Transitional Health Claim Standard 1.1A.2.

¹⁰⁹ See, eg, Helen Dragicevich, Peter Williams and Leisa Ridges, 'Survey of Health Claims for Australian Foods Made on Internet Sites' (2006) 63 *Nutrition & Dietetics: The Journal of the Dietitians Association of Australia* 139. The survey of 1068 websites found 14.5% carried a health claim where 19.7% identified were high level of claims of therapeutic action.

¹¹⁰ Food Standards Australia New Zealand, 'Proposal P293 Nutrition, Health & Related Claims Regulation Impact Statement' (Regulatory Impact Statement, FSANZ, 2012) 6.

¹¹¹ Australian Food and Grocery Council (AFGC) *Code of Practice on Nutrient Claims in Food Labels and in Advertisements* (Code of Practice, AFGC, 1995) <<http://www.foodstandards.gov.au/publications/pages/codeofpracticeonnutr4709.aspx>>.

¹¹² Joint FAO/WHO Codex Alimentarius Commission, *Guidelines for use of nutrition and health claims: CAC/GL 23-1997*, as amended (Rome, Food and Agriculture Organization of the United Nations 2010) recommends *inter alia* at para 8, health claims be based on 'current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognised by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available', and 'Any health claim must be accepted by or be acceptable to the competent authorities' where 'if the claimed effect is attributed to a constituent of the food, there must be a validated method to quantify the food constitute that forms the basis of the claim'.

¹¹³ A 2015 review of 28 jurisdictions revealed Barbados, Canada, Central America, Colombia, Ecuador, Europe, Indonesia, the Republic of Korea and the USA require newly established disease risk reduction claims to be positively assessed by a government authority. Argentina, Brazil, China, Japan and Singapore require approval of all disease risk reduction claims,

TABLE 2: TYPES OF HEALTH CLAIMS AS DEFINED BY JURISDICTION

Claims based on a food health relationship with no mention of a disease (USA and EU) or no mention of a 'serious disease' (Australia/NZ)			
	EU	USA	AUSTRALIA/NZ
DEFINITIONS AND APPLICABLE TERMINOLOGY, BY JURISDICTION	'Article 13.1 health claims' other than those referring to the reduction of disease risk' where health claims described 'the role of a nutrient or other substance in growth, development and the functions of the body, or b) psychological and behavioural functions ... which are included in the [EC list] may be made if based on generally accepted scientific data and well understood by the average consumer'. Article 13.5 health claims are 'new function' claims on a health benefit based on newly developed scientific evidence and/or which include request for the protection of proprietary data. 'Health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.	'Structure/Function' claims describe the effect that a substance has on the structure or function of the body and do not make reference to a disease. 101.93(f) Permitted structure/function statements. Dietary supplement labels or labeling may, subject to the requirements in paragraphs (a) through (e) of this section, bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterise the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims under paragraph (g) of this section. If the label or labeling of a product marketed as a dietary supplement bears a disease claim as defined in paragraph (g) of this section, the product will be subject to regulation as a drug unless the claim is an authorised health claim for which the product qualifies. Section 403(r)(6) of the <i>Food Drug and Cosmetics Act</i> ('FDCA') does not apply to conventional food provided the effects are derived from the nutritive value of the food.	'General Level Health Claim' is 'a health claim that is not a high level health claim'. Health claim means 'a claim which states, suggests or implies that a food or a property of a food has, or may have, a health effect'. Health effect means 'an effect on the human body, including an effect on one or more of the following a) a biochemical process or outcome; b) a physiological process or outcome; c) a functional process or outcome; d) growth and development e) physical performance; f) mental performance; g) a disease, disorder or condition'.
LAW	Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.	21 USC § 343(r)(6) and 21 CFR 101.93.	Australia New Zealand Food Standards Code Standard 1.2.7 s 2.
LEVEL OF REGULATION	EFSA pre-approves food health relationships. EC authorises permitted health claims, including the wording, following EFSA assessment of scientific evidence. Article 13.1 and 13.5 approved health claims are listed for use in Regulation 432/2012.	Structure/function claims are not pre-approved by FDA. Section 403(r)(6) DSHEA or FDCA statements on dietary supplements are notified to FDA within 30 days of marketing. FDA checks dietary supplements for prohibited claims 'to diagnose, mitigate, treat, cure, or prevent disease'.	Two avenues: 1. Pre-approved by FSANZ and there is a list of about 212 food health relationships. Or, 2. Not pre-approved by FSANZ - self-substantiation process with systematic review prescribed. Food health relationship notified to FSANZ. Wording of the claims must not 'alter or contradict the intention of the information'.

	EU	USA	AUSTRALIA/NZ
SCIENTIFIC SUBSTANTIATION	Article 6: '1. Nutrition and health claims shall be based on and substantiated by generally accepted scientific data' and taking into account the totality of the available scientific data, and by weighting the evidence. EFSA's scientific criteria for evaluation similar for Art 13.1, 13.5 and Art 14 health claims.	FDA publishes unenforceable guidance documents to assist industry to substantiate their claims.	Prescribed systematic review process at <i>Standard 1.2.7</i> sch 6 with compliance monitored by state food regulators by requesting dossier of evidence when in breach.
DEFINITION	Article 14 claims: 'reduction of disease risk claim' means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduced a risk factor in the development of a human disease.	'Health claim' means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including 'third party' references, written statements (e.g., a brand name including a term such as 'heart'), symbols (e.g., a heart symbol), or vignettes, characterises the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.	'High Level Health Claim' means a 'health claim that refers to a serious disease or a biomarker of a serious disease'. Serious disease is defined to mean 'a disease, disorder or condition which is generally diagnosed, treated or managed in consultation with or with supervision by a health care professional'.
LAW	Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, Art 14.	21 CFR 101.14(a)(1).	<i>Standard 1.2.7 s 2.</i>
LEVEL OF REGULATION	Food health relationship pre-approved by EFSA. EC authorise health claims for use.	Pre-approved by FDA prior to use.	Food health relationship pre-approved by FSANZ and listed in <i>Standard 1.2.7</i> , for compliant use.
SCIENTIFIC SUBSTANTIATION	Article 6: '1. Nutrition and health claims shall be based on and substantiated by generally accepted scientific data' and taking into account the totality of the available scientific data, and by weighting the evidence. EFSA's scientific criteria for evaluation similar for Art 13.1, 13.5 and Art 14 health claims.	Section 403(r)(3) of the <i>Federal Food, Drug, and Cosmetic Act</i> (the Act) (21 U.S.C. 343(r)(3)) and 21 CFR 101.14(c) Validity requirement. FDA will promulgate regulations authorising a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognised scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence. Significant Scientific Agreement (SSA) Standard at 21 CFR 101.70 provides the petition process.	Systematic review by FSANZ of the food health relationship as provided by <i>Standard 1.2.7</i> sch 6, where the established food health relationship is a 'reasonable conclusion of the systematic review'. Same standard of evidence as required for self-substantiated general level health claims.

self-substantiate food health relationships involving a claimed health effect on ‘a disease, disorder or condition’ as long as the disease is not a ‘serious disease’¹¹⁴ and the claims do not refer to the ‘prevention, diagnosis, cure or alleviation of a disease, disorder or condition’.¹¹⁵ The food business documents its ‘systematic review’¹¹⁶ of the evidence to demonstrate a causal relationship between the food/property of food and the health effect, and certify that the established food health relationship is a ‘reasonable conclusion’ of the review.¹¹⁷

Scientifically substantiating the ‘food-health relationship’ underpinning a health claim is the critical process of objectively evaluating the evidence for a claim, taking into consideration factors such as the existence of human trial data to ensure the claim is true and correct and not likely to mislead consumers. There are already about 212 food health relationships pre-approved by FSANZ to support the making of GLHCs. This removes the uncertainty for consumers over the scientific plausibility of the listed relationships. FSANZ reports that the avenue for self-substantiation of food health relationships is to ‘minimise business risk, and in doing so it promotes innovation’.¹¹⁸ It was determined that

while it is possible that there may be some reduction in consumer benefit arising from a perception of reduced certainty and confidence in GLHCs derived from self-substantiated food health relationships, consumers may also gain additional benefit arising from the higher incentive for industry to innovate. It is therefore the preferred option.¹¹⁹

This position, which maintains a degree of self-regulation in relation to health claims, is in contrast to the regulatory outcome in Europe, discussed below, where the system aims to ‘ensure a *high* level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry’ (emphasis added).¹²⁰ The onus is on Australian and New Zealand consumers to be aware when reading labels and ensure that they understand what the scientific claims actually mean. Moreover, the application of state food regulators’ statutory objectives to monitor compliance with the Food Standards Code and prevent misleading or deceptive conduct in the sale and advertising of food will be critical to limit consumer exposure to this type of food fraud.¹²¹

previously approved claims included. The ‘health foods’ licensing regimes in China, Japan and Singapore require marketers to seek approvals to use disease risk reduction claims. Allie De Boer and Aalt Bast, ‘International Legislation on Nutrition and Health Claims’ (2015) 55 *Food Policy* 61, 65.

114 *Standard 1.2.7 s 2* provides that serious disease means ‘a disease, disorder or condition which is generally diagnosed, treated or managed in consultation with or with supervision by a health care professional’.

115 *Ibid* s 8.

116 *Ibid* sch 6.

117 *Ibid* s 19(1)(d)(ii).

118 Food Standards Australia New Zealand, ‘Proposal P293 Nutrition, Health and Related Claims’ (Regulation Impact Statement, FSANZ, October 2021) 4.

119 *Ibid*.

120 *Health Claims Regulation (EC) 1924/2006* art 1.

121 *Model Food Act 2000 (Cth)* s 1(b).

B Comparison of *Standard 1.2.7* with EU and US Equivalents

1 *European Regulation of 'Superfood' and Related 'Anti-Ageing' Health Claims*

The EU has, somewhat controversially, applied the precautionary principle to protect consumers from health claims not established by substantiation methods good enough to satisfy traditional medical trials, including the 'golden standard' of evidence, the randomised control trial. The EU regime suggests that the use of health claims unsubstantiated to a particular legal standard amounts to misleading conduct requiring regulatory action in the interest of public health. Only European Food Safety Authority (EFSA)-approved food-health relationships, and their authorised health and nutrition claims determined by the European Commission (EC),¹²² are permitted for use in the sale of food.¹²³

The application of the precautionary principle to restrict scientific evidence used in the sale of food to medical trial standards has been criticised because, 'in effect, [it] mandates obscuring scientific information from the general public that could inform about certain benefits of certain products in a much broader context of available scientific knowledge than legally defined.'¹²⁴ The threshold test of 'generally accepted scientific data',¹²⁵ and the scientific rigor applied by the EFSA Scientific NDA Panel,¹²⁶ has challenged the food industry and the basis for making many of the types of health claims observed on açai products in this survey. The EFSA Scientific NDA Panel has rejected the vast majority of food business health claim substantiation dossiers submitted to it,¹²⁷ after weighing assessed evidence for consistency, strength, dose-response, specificity and biological plausibility.¹²⁸

Based on the submitted, assessed evidence, EFSA has since 2010 rejected all 149 attempts to substantiate food health relationships involving the word 'antioxidant', and accepted only one out of 19 industry submissions regarding 'polyphenols'.¹²⁹ The only claim permitted by the EC for polyphenols that reflects the free radical theory is that

¹²² The EU register on nutrition and health claims permitted for use in the sale of foods can be accessed: <<http://ec.europa.eu/nuhclaims/?event=register.home>>.

¹²³ *Health Claims Regulation (EC) 1924/2006* art 10.

¹²⁴ Aalt Bast, William Briggs, Edward Calabrese, Michael Fenech, Jaap Hanekamp, Robert Heaney, Ger Rijkers, Bert Schwitters and Pieternel Verhoeven, 'Scientism, Legalism and Precaution—Contending with Regulating Nutrition and Health Claims in Europe' (2013) 6 *European Food and Feed Law Review* 401.

¹²⁵ *Health Claims Regulation (EC) 1924/2006* art 5.1.

¹²⁶ The European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies is chaired by Albert Flynn and representatives from 21 member states. It conducts the scientific assessment to evaluate health claims and publishes outcomes as scientific opinions in *European Food Safety Authority Journal*.

¹²⁷ See European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies, 'General guidance for Stakeholders on the Evaluation of Article 13.1, 13.5 and 14 Health Claims' (2011) 9 *European Food Safety Authority Journal* 2135.

¹²⁸ A Flynn, 'Scientific Substantiation of Health Claims in the EU' (2012) 71 *Proceedings of the Nutrition Society* 120, 123.

¹²⁹ For a full understanding of all authorised and non-authorised food health relationships, a search of the European Register on Nutrition and Health claims can be performed. See the outcome from a search using these terms at <<http://ec.europa.eu/nuhclaims>>.

'olive oil polyphenols contribute to the protection of blood lipids from oxidative stress'.¹³⁰ The following are examples of unsubstantiated, non-compliant food health relationships, according to the EFSA Scientific Opinions of industry substantiation evidence:

Fruits and 'antioxidants help strengthen our body's natural defences against oxidative stress' and 'protection of DNA, proteins and lipids from oxidative damage';¹³¹

Vegetables 'protect you from free radicals; protect your cells and tissues from oxidation; antioxidants help strengthen our body's natural defences against oxidative stress';¹³²

Polyphenols from processed fruits and tea: 'protection of DNA, proteins and lipids from oxidative damage';¹³³

Polyphenols 'contained in this produce ensure antioxidant action; help prevent tissue oxidation; help guard against oxidation caused by free radicals; have an antioxidant effect; help mop up free radicals in cells/antioxidants';¹³⁴

Anthocyanin 'contains naturally occurring antioxidants, which may help to protect against the damage caused by free radicals, as part of a healthy lifestyle'¹³⁵

130 European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies, 'Scientific Opinion on the Substantiation of Health Claims Related to Polyphenols in Olive and Protection of LDL Particles from Oxidative Damage' (2011) 9(4) *European Food Safety Authority Journal* 2033.

131 European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies, 'Scientific Opinion on the Substantiation of Health Claims Related to Various Food(s)/Food Constituent(s) and Protection of Cells from Premature Ageing (ID 1668, 1917, 2515, 2527, 2530, 2575, 2580, 2591, 2620, 3178, 3179, 3180, 3181, 4329, 4415), antioxidant activity, antioxidant content, and antioxidant properties (ID 857, 1306, 2515, 2527, 2530, 2575, 2580, 2591, 2629, 2728, 4327, 4365, 4380, 4390, 4394, 4455, 4464, 4507, 4694, 4705), protection of DNA, proteins and lipids from oxidative damage (ID 1196, 1211, 1216, 1306, 1312, 1440, 1441, 1666, 1668, 1692, 1900, 1914, 1948, 2023, 2158, 2517, 2522, 2527, 2575, 2591, 2620, 2637, 2639, 2663, 2860, 3079, 3276, 3564, 3818, 4324, 4329, 4351, 4397, 4416, 4424, 4507, 4527, 4528, 4542, 4611, 4629, 4659), and bioavailability of anthocyanins in black currants (ID 4220) pursuant to Article 13(1) of Regulation (EC) No 1924/2006' (2010) 8(10) *European Food Safety Authority Journal* 1752, 17.

132 Ibid 18.

133 Ibid 20.

134 European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies, 'Scientific Opinion on the substantiation of health claims related to flavonoids and ascorbic acid in fruit juices including berry juices (ID 1186); flavonoids from citrus (ID 1471); flavonoids from Citrus paradisi Macfad. (ID 3324, 3325); flavonoids (ID 1470, 1693, 1920); flavonoids in cranberry juice (ID 1804); carotenoids (ID 1496, 1621, 1622, 1796); polyphenols (ID 1636, 1637, 1640, 1641, 1642, 1643); rye bread (ID 1179); protein hydrolysate (ID 1646); carbohydrates with a low/reduced glycaemic load (ID 476, 477, 478, 479, 602) and carbohydrates which induce a low/reduced glycaemic response (ID 727, 1122, 1171); alfalfa (ID 1361, 2585, 2722, 2793); caffeinated carbohydrate-containing energy drinks (ID 1272); and soups (ID 1132, 1133) pursuant to Article 13(1) of Regulation (EC) No 1924/2006' (2011) 9(4) *European Food Safety Authority Journal* 2082, 10.

135 European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies, 'Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) and protection of cells from premature aging, antioxidant activity, antioxidant content and antioxidant properties, and protection of DNA, proteins and lipids from

The EFSA Panel determined that the required level of scientific consensus relating to the free radical theory of ageing (specifically, oxidative damage) exists for vitamins and minerals where the relationships appear entrenched in nutritional science textbooks.¹³⁶ The EFSA Panel determinations reflect our analysis on ‘polyphenols’, ‘free radicals’, and ‘antioxidants’, and substantiated food health relationships. It opined that the available evidence of *in vitro* studies, referring to modeling systems and plasma-based *in vitro* studies used to support claims of antioxidant status, capacity and physiological effect in humans, is inadequate to establish causal conclusions between the food and a health effect. Sufficient human-based trials were absent and crucial for substantiation. Prized food components (‘antioxidants’) and health effects such as ‘anti-ageing’ were inadequately characterized for measurement; claims were general and lacked specificity, in contravention with *Health Claims Regulation (EC) No 1924/2006*.

This suggests that many of the claims observed in our açai berry labelling study would not be allowed onto the market under a precautionary system like that in the EU.

2 United States Regulation of Health and Related Claims

In the US, ‘health claims’ on food that expressly, or by implication, characterise a relationship between any substance and a disease, or health related-condition, must be approved by the US Food and Drug Administration (FDA) before market.¹³⁷ The FDA is guided by the principle of ‘significant scientific agreement’.¹³⁸ Following the approval of a health claim, the FDA lists the health claim for use by industry.¹³⁹ On the other hand ‘structure/function claims’¹⁴⁰ are similar in status to self-substantiated GLHCs under *Standard 1.2.7* and do not require authorization prior to marketing.¹⁴¹

With the most liberal approach towards regulating health benefits claimed in the sale of food and dietary supplements (in that jurisdiction), much of the literature argues that there should be a revolutionary shift from the self-regulatory approach to substantiating claims, to a reforming proactive approach—as in the EU—to protect consumers from misleading conduct or false representations.¹⁴²

oxidative damage pursuant to Article 13(1) of Regulation (EC) No 1924/2006’ (2010) 8(2) *European Food Safety Authority Journal* 1489.

¹³⁶ European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies, ‘Scientific Opinion Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health’ (2011) 9(12) *European Food Safety Authority Journal* 2474, 3.2.

¹³⁷ 21 C.F.R. 101.14(a)(1)(1).

¹³⁸ See Office of Nutrition, Labelling and Dietary Supplements, Food and Drug Administration, *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims—Final* (FDA 2009) <<http://www.fda.gov>>.

¹³⁹ See U.S. Food & Drug Administration, *Health Claims Meeting Significant Scientific Agreement (SSA)* (10 May 2015) <http://www.fda.gov/Food/%20IngredientsPackagingLabeling/LabelingNutrition/ucm2006876.htm#Approved_Health_Claims>.

¹⁴⁰ *Dietary Supplement Health and Education Act of 1994* s101.93(f).

¹⁴¹ 21 U.S.C 343(r)(6) and 21 C.F.R. 101.93.

¹⁴² See, for example, Richard Nowak, ‘DSHEA’S Failure: Why a Proactive Approach to Dietary Supplement Regulation Is Needed to Effectively Protect Consumers’ (2010) *University of Illinois Law Review* 1045.

C Evaluation of *Standard 1.2.7's* Capacity to Prevent and Control Food Fraud in Cases of Overreaching Superfood Health Claims

With full implementation of *Standard 1.2.7* from the start of 2016, the marketplace should see a reduction in many of the types of health claims observed on açai product labelling and in advertising. Any future GLHCs that relate to alleged causal relationships between polyphenols or other phytochemicals and a health effect will require self-substantiation. The pre-approved food-health relationships listed in the Standard that echo the free radical theory of ageing – those that refer to ‘free radicals’¹⁴³ and ‘oxidative stress’¹⁴⁴ – are limited to some well-defined and characterised vitamins and minerals. To date, there have been no food health relationships established through self-substantiation and involving polyphenols (in açai or indeed any other foods) or any claimed ‘anti-ageing’ health effects notified to FSANZ.¹⁴⁵ Under *Standard 1.2.7*, any claims of food health relationships involving a ‘serious disease or a biomarker of a serious disease’ will pursue a ‘high level health claim variation’¹⁴⁶ for assessment of the evidence by FSANZ before market. As identified above, *Standard 1.2.7* departs from the international approach towards pre-market approval of all disease related claims and introduces a defining concept that distinguishes ‘disease’ from ‘serious disease’.¹⁴⁷ The effect of this permission may be the subject of future research. Indeed, the same may be said of whether State regulators will be successful at identifying non-compliant, self-substantiated general health claims that mention a ‘disease, disorder or condition (or biomarker thereof) that is generally diagnosed, treated or managed in consultation with or with supervision by a health care professional’.¹⁴⁸

The introduction of regulatory controls around nutrient content claims and comparative marketing will limit the to-date seemingly unfettered use of ambiguous terms in comparative nutrition content claims such as ‘high in anti-oxidants’, ‘high concentration of polyphenols’ and ‘high in phytochemicals’.¹⁴⁹ Within the comprehensive framework however, new ambiguities may emerge to hinder its consistent implementation and therefore its effectiveness in achieving consumer protection objectives.

Some definitions central to the standard’s effectiveness are seemingly incongruent with scientific proof requirements. The inclusion of ‘*may have* a health effect’ to the

¹⁴³ *Standard 1.2.7* sch 4 s 5 provides copper, zinc and manganese may protect cell damage from ‘free radicals’; vitamins C and E ‘contributes to cell protection from free radical damage’; and selenium is ‘necessary for cell protection from some types of free radical damage’.

¹⁴⁴ *Ibid.* The permitted food-health relationships related to ‘oxidative stress’ is limited to riboflavin and the health effect: ‘contributes to the protection of cells from oxidative stress’.

¹⁴⁵ FSANZ publishes notified food-health relationships to <<http://www.foodstandards.gov.au>>.

¹⁴⁶ *Food Standards Australia New Zealand Act 1991* (Cth) s 4.

¹⁴⁷ De Boer and Bast, above n 113, 65.

¹⁴⁸ *Standard 1.2.7* s 2.

¹⁴⁹ *Ibid* s 12, sch 4 s 3. Antioxidants, phytochemicals and polyphenols (or similar) are not included in the list of properties of food to which nutrient content claims can be made. Permitted as ‘presence/absence’ claims such as ‘contains polyphenols’, where that is true and correct.

definition of health claim¹⁵⁰—absent from the European definition¹⁵¹—deviates from the certainty provided in the EU system and appears prima facie inconsistent with the high standard of proof demanded from the prescribed systematic review that ‘a causal relationship has been established’¹⁵² and ‘the notified relationship is a reasonable conclusion of the systematic review’.¹⁵³ Further, unlike in the EU where the EC authorises the actual words used, nothing in *Standard 1.2.7* prescribes the words used in a health claim.¹⁵⁴ The operation of the US regime is reportedly challenged by the ambiguity around legal terms, definitions and unenforceable substantiation requirements for claims that do not refer to a disease.¹⁵⁵ The FDA has issued unenforceable substantiation guidance documents,¹⁵⁶ whereas *Standard 1.2.7* removes ambiguity as to the legal standard to substantiate a food-health relationship, listing the necessary elements for a systematic review as elements of legal compliance for local enforcement.¹⁵⁷

Challenges to regulatory enforcement of *Standard 1.2.7* include the fact that there is likely to be minimal regulatory surveillance of any unsubstantiated claims once products are in the marketplace. Food regulatory agencies are honed to ‘food safety’.¹⁵⁸ State food regulators and delegated local Councils¹⁵⁹ responsible for monitoring compliance¹⁶⁰ operate a ‘graduated application’ of enforcement measures, progressing from warnings and mediation to prosecution in the most severe cases.¹⁶¹ Authorised

¹⁵⁰ Ibid s 2.

¹⁵¹ *Health Claims Regulation (EC) 1924/2006* art 2.5 provides that health claim ‘means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health’.

¹⁵² *Standard 1.2.7* sch 6 s 2(g).

¹⁵³ Ibid s 19(1)(d)(ii).

¹⁵⁴ Ibid s 10. See also *Standard 1.1.1* s 8(2), which provides ‘if a provision of the Code requires a statement other than a warning statement to be used, that statement may be modified’ and ‘any modification must not contradict or detract from the effect of the statement’.

¹⁵⁵ *Dietary Supplement Health and Education Act 1994* s 343(r)(6)(B) provides a manufacturer must be able to substantiate its claims. How a claim is to be substantiated is not provided in law.

¹⁵⁶ Food and Drug Administration, *Guidance for Industry, Substantiation for Dietary Supplement Claims Made under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act* (Guidance, FDA, 2008).

¹⁵⁷ *Standard 1.2.7* sch 6.

¹⁵⁸ See, eg, Food Standards Australia New Zealand, ‘P293 Nutrition, Health and Related Claims Summary of Submissions to the March 2009 Consultation Paper—Preferred Options’ (Submissions, Food Standards Australia New Zealand, 2009) 22, where the Department of Health, Victoria submitted, ‘General Level Health Claims are marketing tools. The inclusion of a Standard to regulate marketing is a new approach; current food regulation is not designed to deal with this and proportionate enforcement tools would be needed’.

¹⁵⁹ See, eg, *Food Act 2003* (NSW) s 109E.

¹⁶⁰ *Standard 1.2.7* s 19(d) provides that if requested by a relevant authority, a person who notified FSANZ must provide records that demonstrate the systematic review was conducted in accordance with Schedule 6 and the notified relationship is a reasonable conclusion of the systematic review.

¹⁶¹ Implementation Subcommittee for Food Regulation, above n 43.

officers have limited time for monitoring health claims and, understandably, given limited resources, prioritise food safety issues.¹⁶²

While the new *Standard 1.2.7* is an advance on the previous regulatory situation regarding the marketing of foods, as we have argued, industry self-regulation is limited in a context of healthism and gastro-anomy where consumers look more and more to labels to inform them in their self-care. The new *Standard 1.2.7* in which industry self-regulation is to be the subject to regulatory supervision will require much more sophisticated monitoring and enforcement of self-substantiated industry claims.¹⁶³ State food regulators must therefore identify food fraud as a strategic regulatory policy aim and demonstrate how each state is effectively fulfilling the statutory objective¹⁶⁴ to prevent misleading or deceptive conduct – by monitoring the use of health claims in the sale of food in the interest of public health.

IV CONCLUSION

Our analysis of anti-ageing health claims about açai product labelling and advertising in Australia showed that the combination of confusing scientific terms and claims and an exotic backstory may make açai berry products particularly appealing to consumers when marketed as ‘superfoods’. Yet, many of the anti-ageing health claims made on these products are arguably false, misleading or deceptive. They exaggerate the evidence base for physiological benefits from anti-oxidants and the free radical theory of ageing, and they ignore the fact that no unique evidence supports the choice of more expensive ‘superfood’ products based on exotic fruit when the same claimed benefits can be obtained from eating a variety of less expensive, more available fresh fruit and vegetables. In the social context of ‘healthism’ and ‘gastro-anomy’, where there is heightened anxiety about ensuring one eats healthy foods, but little clear, trustworthy guidance about what to eat and when, overreaching health claims may serve to compromise consumer choice and distort public health messages. Food industry actors often dominate the information consumers receive about health food choices through product labelling and advertising.

In this context, it is an important aspect of public health promotion that Australian food policy and regulation adequately prevent and control ‘food fraud’ including the making of false or misleading statements for economic gain. We have shown that a consumer protection regulator, even a powerful and effective regulatory like the ACCC, is not equipped to ensure that food industry actors meet appropriate and high standards of scientific evidence before making health claims on processed foods. The TGA does not apply to food and so does not regulate this area. Rather, it is Australia’s food labelling standards regime, with standards set by FSANZ and monitored and enforced by state food authorities, that is best equipped to set appropriate standards and proactively ensure that industry complies with those standards in food labelling and marketing.

¹⁶² Deanne Condon-Paoloni, Heather Yeatman and Elizabeth Grigonis-Deane, ‘Health-Related Claims on Foods Labels in Australia: Understanding Environmental Health Officers’ Roles and Implications for Policy’ (2013) 18(1) *Public Health Nutrition* 81.

¹⁶³ See the discussion of what is required for effective ‘meta-regulation’ (ie the government regulation of industry self-regulation) in Christine Parker, *The Open Corporation* (Cambridge University Press, 2002), 245–92.

¹⁶⁴ *Model Food Act 2000* (Cth) s 1.

We have shown that Australia's new *Standard 1.2.7* does in substance address the need for a high and appropriate level of scientific evidence before health claims can be made in labelling and marketing. Applying this standard to the claims we observed on açai superfood products suggests that a number of claims would now be inappropriate. However, unlike the EU regulation, *Standard 1.2.7* allows industry self-substantiation of some claims. Moreover, its effectiveness also relies on state food authorities to actively monitor compliance and take enforcement action where unsubstantiated claims are made, and it is unclear whether state food authorities are adequately resourced to monitor the compliance of labels and advertising, undertake investigations, identify breaches accurately and enforce the requirements. The ambiguity of regulatory standards and the lack of monitoring with effective enforcement have allowed spurious health claims to flourish up to 2016. In the future, regulators should ensure that the onus is on business to substantiate anti-ageing health claims according to a legal standard of scientific proof so as to prevent misleading conduct and protect public health.