

New exotic fruits from Brazil and their use in soft drinks: What health claims can be made in the EU from these novel foods?

John A. Wilkinson and Kesia Trench

Abstract

New and unusual exotic fruits introduced into the European Union (EU) will be much more common as a consequence of the revised Novel Foods* Directive for Traditional Foods (*EC Regulation No. 2015/2283*), but what health claims can soft drink manufacturers make from these potential new ingredients? In the previous paper (*Wilkinson 2016*) the possible effects of the revised EU Novel Foods Directive on traditional foods (*Ingar et al. 2014*) were discussed with relation to exotic fruits from Brazil and their possible use in the soft drinks industry, primarily as fruit juices and for flavouring. The authors visited Brazil and interviewed producers and distributors of exotic fruits and, combining this with scientific literature searches, came up with a list of ten possible new fruits (i.e., ‘new’ to the EU), that are likely to be considered novel foods in the EU and that could be eligible for use in soft drinks primarily for their flavour, potential health benefits, texture and taste.

In this paper the type of health claims that can be made with soft drinks containing such new exotic fruits and fruit juices derived from them are explored. This is undertaken by focusing on a selected number of important nutrients and their quantities found in such fruits and then correlating this with the subsequent types of health claims that can be made or allowed, from an EU perspective.

* The definition of a novel food in the EU is ‘any food that was not used for human consumption to a significant degree within the EU before the 15th May 1997’ (*EC Regulation No. 2015/2283*).



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Fruits like atemoya offer significantly more potassium than bananas.



The authors visited Brazil and interviewed producers and distributors of exotic fruits.

Introduction

New fruits, i.e. new botanical species for use in soft drinks in the EU, have in the past 20 years or so been a very rare occurrence mainly due to the expensive costs and ‘red tape’ for approval under the old Novel Foods Directive (*Wilkinson and Hall 2007; Wilkinson and Hall 2008*). This directive also required extensive toxicology studies for approval (including studies on exotic edible fruits unknown to the EU) and largely ignored the inclusion of safety data from such foods which could or was collated from safe human consumption over decades of use. Hence, the average costs to achieve novel foods approval was around EUR 7 million until an innovative model was developed which brought the costs down to less than EUR 250,000 and in the future, maybe even down to EUR 10,000 - 50,000 if all the analytical data and supporting traditional use have been completed (*Wilkinson 2006*).

This new approach, combined with lobbying and various scoping and review papers (e.g., *Ingar et al. 2014*), led to the emergence of a new regulatory category/amendment for novel foods known as ‘traditional foods’ (*EC Regulation No. 2015/2283*). These are defined in the EU as foods such as fruits, vegetables and juices which have at least 25 years’ traditional use from the country of origin but which are new to the EU and have not been traded to a significant degree in the EU prior to 1997. This new amendment comes fully into force in January 2018.

EU Health Claims

Once novel foods approval has been achieved for specific exotic fruits and fruit juices as ‘traditional foods’ it is possible (on the understanding that certain conditions of use are met) to also use generic health claims such as – vitamin C contributes to the reduction of tiredness and fatigue’ on the labeling of soft drinks sold in the EU, depending on the amount of a particular nutrient

or vitamin that is found in a specific fruit/ fruit juice/soft drink.

As defined and specified by EU legislation, health claims can only be made for foods and drinks that are considered a source of that nutrient. In other words, the product must contain at least a significant amount of the vitamin or mineral in question so it gains the status of 'a source of' before an approved generic health claim can be used. Such specified nutrients and substances may naturally be found in foods/fruits or may be added to the manufactured product as specified by regulations (*EC Regulation No. 1924/2006*; *EU Council Directive (90/496/EEC)*; *EC Regulation No. 1925/2006*).

So what does this mean to the industry when developing products with new exotic fruits, juices and ingredients or new food uses? What are some of the possible generic health claims that can be made for nutrients such as vitamins and minerals found in approved or existing exotic fruits or fruit juices sold in the EU?

A non-exhaustive literature search was undertaken on the exotic Brazilian fruits highlighted previously (*Wilkinson 2016*) and which are reproduced below, to identify possible health claims that could be made by using these fruits in drinks manufactured by the soft drinks industry:

Popular name	Scientific name
Araza, araçá-boi	<i>Eugenia stipitata</i>
Atemoya	<i>Annona cherimola</i> X <i>A. squamosa</i>
Bacuri	<i>Platonia insignis</i>
Camu-camu	<i>Myrciaria dubia</i>
Carambola, starfruit	<i>Averrhoa carambola</i>
Kiwano	<i>Cucumis metuliferus</i>
Mangaba	<i>Hancornia speciosa</i>
Megafauna	<i>Cassia grandis</i>
Siriguela	<i>Spondias purpurea</i>
Umbu	<i>Spondias tuberosa</i>
Umbu-caja	<i>Spondia bahiensis</i>

A selection of nutrients/vitamins such as vitamin C, manganese and iron were identified from the above fruits that had a content high enough to be able to make a health claim. (Note: The amount of nutrient found in the final product/soft drink formulation will obviously depend on how much of a particular fruit is used to make the soft drink, e.g., whether it is a part of fruit, the juice or for example, a diluted juice or pulped fruit is used).

The following tables list a number of different health claims that can be made along with the content needed for each nutrient and the source of the nutrient from a particular fruit, based on literature values only. The nutrient/vitamin levels listed in each section from these exotic Brazilian fruits are also compared to 'non novel foods/ fruits' that are well known in the Western world such as bananas, canteloupe (a type of melon), currants etc.

If a company wants to use a particular fruit/fruit juice in a formulation, some calculations will need to be made, based on the amount of each nutrient that is present in the final formulated product. Although a laboratory analysis is not needed to state the amount of nutrient/vitamins in a particular final product, it



At 2075 mg/100g of fruit, Camu-camu contains a high level of vitamin C.

is still advisable to do so rather than rely just on literature values cobbled together with data sheets from each individual ingredient in a particular formulated soft drink.

Health claims for exotic fruits with regard to a specified nutrient/vitamin.

From the above list of exotic Brazilian fruits and so called 'superfruits'* the following nutrients/vitamins together with their amounts and associated claims are tabulated below. It is required by the EU health claims legislation that fruit juices and soft drinks containing these fruits as ingredients will also need to have the minimum required levels of the desired nutrient (or mineral or vitamin), so that such beverages can be considered a 'source of' or a 'high source of' for that nutrient, for a health claim to be made.

*For an explanation of the meaning of superfruits, see *Wilkinson 2013*.

Health claims for vitamin C

Table 1 lists some fruits with their vitamin C content and associated health claims. Siriguela, umbu-caja and bacuri typically have circa 30mg of vitamin C/100g of fruit, which is considered to be high source of this vitamin. This value is comparable to canteloupe (*Cucumis melo*), a well known variety of melon in the western world. Other fruits contain even more vitamin C: araza has twice, mangaba has four times but camu-camu has almost 21 times (2075 mg/100g of fruit) the amount of vitamin C as in canteloupe (31mg of vitamin C/100g of fruit according to *Lee and Vader 2000*).

The following is a selection of the possible generic claims that can be made from the above examples:

- Vitamin C contributes to the protection of cells from oxidative stress.
- Vitamin C contributes to the reduction of

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As defined and specified by EU legislation, health claims can only be made for foods and drinks that are considered a source of that nutrient.

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tiredness and fatigue.
• Vitamin C contributes to normal energy-yielding metabolism.

Health claims for Potassium

Table 2 lists some fruits which contain potassium. Bananas (*Musa acuminata* and other species) are the most usual fruit sources of potassium with typically 320mg/100g of fruit (Mohapatra et al. 2010). Fruits like atemoya and bacuri offer significantly more potassium than bananas: 551 and 2795mg/100g respectively. Ripe bacuris are likely a ‘high’ source of potassium, containing nearly nine times as much potassium as bananas, and nearly 13 times as much if



Red and green siriguela fruit.

Table 1: Selected fruits with vitamin C content and examples of generic health claims

Popular name	Scientific name	Vitamin C content (mg/100g of fruit)	Amount required to make a ‘source of’ claim in drinks in the EU (mg)	Amount required to make a ‘high’ claim in drinks in the EU (mg)	Selected examples of allowed generic health claims for vitamin C*
Siriguela (Quintão 2015)	<i>Spondias purpurea</i>	27	12	24	Vitamin C increases iron absorption
Umbu-caja (Castro and Rybka 2015)	<i>Spondia bahiensis</i>	30	12	24	Vitamin C contributes to the normal function of the immune system
Bacuri (Bezerra et al. 2005)	<i>Platonia insignis</i>	33	12	24	Vitamin C contributes to normal energy-yielding metabolism
Araza (de Souza Paglarini et al. 2015)	<i>Eugenia stipitata</i>	66	12	24	Vitamin C contributes to the reduction of tiredness and fatigue
Mangaba (ageitec online)	<i>Hancornia speciosa</i>	140	12	24	Vitamin C contributes to normal energy-yielding metabolism
Camu-camu (Alkeret al. 2011)	<i>Myrciaria dubia</i>	2075	12	24	Vitamin C contributes to the reduction of tiredness and fatigue

*(each individual claim above could apply to any fruit which qualifies to make a claim of ‘source of’ or ‘high’ claim)

Table 2: Selected fruits with potassium and examples of generic health claims

Popular name	Scientific name	Potassium content (mg/100g of fruit)	Amount required to make a ‘source of’ claim in drinks in the EU (mg)	Amount required to make a ‘high’ claim in drinks in the EU (mg)	Selected examples of allowed generic health claims for potassium*
Umbu-caja (Castro and Rybka 2015)	<i>Spondia bahiensis</i>	150	300	600	Minimum content level of potassium is not present in the fruit. No health claim can be made
Atemoya (Leterme et al. 2006)	<i>Annona cherimola</i> X <i>A. squamosa</i>	551	300	600	Potassium contributes to normal muscle function
Bacuri (Aguiar 2006)	<i>Platonia insignis</i>	2795 (ripe yellow)	300	600	Potassium contributes to the maintenance of normal blood pressure
Bacuri (Aguiar 2006)	<i>Platonia insignis</i>	4268 (unripe green)	300	600	Potassium contributes to normal functioning of the nervous system

*(each individual claim above could apply to any fruit which qualifies to make a claim of ‘source of’ or ‘high’ claim)

Table 3: Mangaba and bacuri as examples of sources of iron and selected generic health claims

Popular name	Scientific name	Iron content (mg/100g of fruit)	Amount required to make a ‘source of’ claim in drinks in the EU (mg)	Amount required to make a ‘high’ claim in drinks in the EU (mg)	Selected examples of allowed generic health claims for iron*
Mangaba (ageitec online)	<i>Hancornia speciosa</i>	2.8	2.1	4.2	Iron contributes to the reduction of tiredness and fatigue
Bacuri (Bezerra et al. 2005)	<i>Platonia insignis</i>	53.7	2.1	4.2	Iron affects activity of heart, liver and muscles

*(each individual claim above could apply to any fruit which qualifies to make a claim of ‘source of’ or ‘high’ claim)

the bacuri fruit is unripe (assuming green bacuris are usually consumed).

The following is a selection of the possible generic claims that can be made from the above examples:

- Potassium contributes to the maintenance of normal blood pressure.
- Potassium contributes to normal muscle function.
- Potassium contributes to normal functioning of the nervous system.

** Umbu-caja was included in the table as a counter-example: umbu-caja does not contain enough potassium so no generic health claims can be made as ‘a source of’.

Health claims for iron

Table 3 lists mangaba and bacuri as sources of iron. Mangaba is a likely ‘a source of’ iron with 2.8 mg/100g of fruit, comparable to well known blueberries (*Vaccinium* Section *Cyanococcus*) with 2.2 mg (USDA database). Bacuri is a likely ‘high’ source of iron: it contains 13 times (53.7 mg/100g of fruit) the minimum amount of iron required for the ‘high’ claim (4.2 mg/100g of fruit) and 26 times more than a ‘source of’ requirement (2.1 mg/100g of fruit).

The following is a selection of the possible generic claims that can be made from the above examples:

- Iron affects activity of heart, liver and muscles.
- Iron contributes to the reduction of tiredness and fatigue.
- Iron contributes to the normal function of the immune system.

Health claims for Manganese

Table 4 lists several fruits containing manganese. Both bacuri and starfruit are likely to be considered a ‘source of’ manganese, containing at least the minimum amount required for that claim (0.2 mg/100g of fruit), with some batches of starfruit likely to be a ‘high’ source of that mineral (0.61). The unripe green fruit of bacuri could also be a ‘high’ source of manganese (0.64), assuming it is usually consumed as food or drink in the

unripe form in the country of origin. However, the content of this mineral in these fruits is comparatively low compared to well known fruits in the EU such as muscadine grapes (1.97mg/100g) and blackberries (1.2mg/100g) (USDA database).

The following is a selection of the possible generic claims that can be made from the above examples:

- Manganese contributes to the maintenance of normal bones.
- Manganese contributes to the normal formation of connective tissue.
- Manganese contributes to normal energy-yielding metabolism.
- Manganese contributes to the protection of cells from oxidative stress.

Health claims for other minerals: calcium, phosphorous, magnesium and zinc.

Table 5 lists mangaba and bacuri as fruits which contain the following minerals: calcium, phosphorous, magnesium and zinc.

Mangaba was highlighted earlier as a fruit source for vitamin C and a likely source of iron. It is also a likely 'a source of' zinc (0.9 mg/100g of fruit), and much greater than well known fruits such as redcurrants (*Ribes rubrum*, 0.23mg), common figs (*Ficus carica*, 0.15mg) and kiwifruit (*Actinidia* various cultivars, 0.14mg) per 100g of fruit (USDA database).

Bacuri is unique from the selected fruits examined in this paper, as a likely 'high source of' not one or two but six minerals: calcium (169 mg/100g of fruit, compared to oranges (*Citrus sinensis*) with 70 mg/100g (with peel) according to the USDA database), phosphorus, magnesium (122 mg/100g of fruit, compared to passion fruit (*Passiflora edulis*) with 29 mg of magnesium/100g according to the USDA database), as well as potassium, iron, manganese which were discussed earlier.

The following is a selection of the possible generic claims that can be made from the above examples:

- Zinc contributes to normal DNA synthesis.
- Zinc contributes to the maintenance of normal skin.
- Zinc contributes to the maintenance of normal vision.
- Calcium contributes to normal blood clotting.
- Calcium contributes to normal neurotransmission.
- Calcium contributes to the normal function of digestive enzymes.
- Magnesium contributes to electrolyte balance.
- Magnesium contributes to normal functioning of the nervous system.
- Magnesium contributes to normal protein synthesis.
- Magnesium contributes to the maintenance of normal bones.

Conclusions

The amended EU Novel Foods Directive containing the category of 'traditional foods' will open up a whole new opportunity for the soft drinks industry. A plethora of new fruits and juices will be available once companies have obtained them via the low cost and a fast track to novel foods approval.



Brazilian fruit market.

Table 4: Selected fruits with manganese and examples of generic health claims

Popular name	Scientific name	Manganese content (mg/100g of fruit)	Amount required to make a 'source of' claim in drinks in the EU (mg)	Amount required to make a 'high' claim in drinks in the EU (mg)	Selected examples of allowed generic health claims for manganese*
Carambola (starfruit) (Aguilar 2006)	<i>Averrhoa carambola</i>	0.23 - 0.61	0.2	0.4	Manganese contributes to the protection of cells from oxidative stress
Bacuri (Bezerra et al. 2005)	<i>Platonia insignis</i>	0.34 (ripe yellow)	0.2	0.4	Manganese contributes to the maintenance of normal bones
Bacuri (Bezerra et al. 2005)	<i>Platonia insignis</i>	0.64 (unripe green)	0.2	0.4	Manganese contributes to the normal function of connective tissue

*(each individual claim above could apply to any fruit which qualifies to make a claim of 'source of' or 'high' claim)

Table 5: Selected fruits with other minerals (calcium, phosphorous, magnesium and zinc) and examples of generic health claims

Popular name	Scientific name	Mineral content (mg/100g of fruit)	Amount required to make a 'source of' claim in drinks in the EU (mg)	Amount required to make a 'high' claim in drinks in the EU (mg)	Selected examples of allowed generic health claims for phosphorus*
Mangaba (ageitec online)	<i>Hancornia speciosa</i>	0.9 Zinc	0.8 Zinc	1.6 Zinc	Zinc contributes to normal macronutrient metabolism
Bacuri (Bezerra et al. 2005)	<i>Platonia insignis</i>	169 Calcium	60 Calcium	120 Calcium	Calcium contributes to normal blood clotting
Bacuri (Bezerra et al. 2005)	<i>Platonia insignis</i>	122 Magnesium	56.25 Magnesium	112.5 Magnesium	Magnesium contributes to normal protein synthesis
Bacuri (Bezerra et al. 2005)	<i>Platonia insignis</i>	155 Phosphorous	52.5 Phosphorous	105 Phosphorous	Currently, there seem to be no generic health claims authorised for phosphorus

*(each individual claim above could apply to any fruit which qualifies to make a claim of 'source of' or 'high' claim)

As this paper demonstrates, companies will also be able to make a number of generic health claims on the labeling of these exotic fruits and juices found in Brazil, such as 'Vitamin C increases iron absorption' and 'Vitamin C contributes to the reduction of tiredness and fatigue'. The advantages are that, with such generic health claims, a company does not have to file a dossier or obtain regulatory approval for the health claim as long as compliance, in terms of the amount and source as discussed in this article, is achieved.

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It is hoped that this article will help stimulate and encourage soft drink manufacturers to develop new drinks based on the largely untapped 'botanical diversity' from around the world.

The number of new fruits highlighted in this article are just a small number compared to the potential hundreds if not thousands of edible fruits that could come from the estimated 250,000 to 750,000 plant species in Brazil alone. Of course this is just the 'tip of the iceberg' in terms of the number of new exotic fruit juices that could be available in the EU over the coming years as manufacturers seek new and undiscovered fruits, not just from Brazil but other regions of the world such as Asia, Africa, Australia, Russia and other parts of South America.

It is hoped that this article will help stimulate and encourage soft drink manufacturers to develop new drinks based on the largely untapped 'botanical diversity' from around the world and to be able to add health claims to the labeling of their products not just from these new exotic fruits but also from existing 'not novel' fruits that are currently marketed in the EU at the present time. ■

Dr John Wilkinson BSc DIC PhD

Dr Wilkinson is a Phytochemist and Pharmacognosist and an expert on the regulatory approval of supplements, herbal medicines, herbal teas and novel foods. He has been a consultant on the regulatory approval of natural products in the EU and the USA for over 20 years. He also established the world's first Herbal Medicine BSc degree in Herbal Medicine in the UK in 1994 where he was Senior Lecturer in Pharmacognosy and Phytochemistry. Prior to this he was awarded the prestigious SERC NATO postdoctoral research fellowship and worked with the Nobel Prize winner George Olah in California, USA, after obtaining his PhD in Organic Chemistry at Imperial College, London.

John provides strategic regulatory advice to companies from targeted one hour teleconferencing problem solving sessions to full dossier submissions for novel foods, supplements, food additives, health claims and labelling. He also undertakes new product development specialising in natural product derived ingredients and is a specialist writer on new ingredients in the natural products industry. He also undertakes original research and gives lectures on "molecular synergy effects of botanical extracts" and their effects in health, medicine and in ecology.

Kesia Trench BSc MSc

Kesia has a degree in Biological Sciences, a masters in Natural Resources Management and a passion for natural products. She previously worked at Defra, London UK as a regulatory and policy adviser primarily in marine conservation but now works with Dr Wilkinson and other experts in the regulatory approval of natural products in the EU and elsewhere. She speaks 5 languages fluently and also offers scientific translation services for business meetings, translation of scientific documents and related regulatory work requiring knowledge of other languages e.g., searching EU databases in Spanish, Portuguese, German, Italian and English.

*Dr John Wilkinson is Scientific Adviser to Soft Drinks International.
www.drjohnwilkinson.co.uk*

www.kesiatrench.com

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