



# *Where Are Berries on the Health Claims Research Pyramid ?*

Part 2 of 2



Spoon yourself some health!  
Eat colorful whole foods.

[follow the [Wikipedia](#) links]

[Read Part 1 here](#)

Like Indiana Jones, every manufacturer of berry and superfruit products is after the [Holy Grail](#) -- a health claim approved by a regulatory agency like the [FDA](#).

In simple terms, a [health claim](#) would prove the berry or one or more of its phytochemicals has a direct effect on health either of a specific organ or general health of the person.

Another way of looking at it is the product would be deemed *required for health* so would get "[essential nutrient](#)" designation with a recommended [Dietary Reference Intake](#) value as vitamins and minerals have.

*Here's a point many miss:*

no berry or superfruit phytochemical has nutrient designation.

Not anthocyanins, not flavonoids, not ellagic acid,  
not \_\_\_\_ -- you fill in the blank.



Cranberries (*Vaccinium macrocarpon* L.) and cranberry juice,  
in step 4 of the research pyramid -- human clinical trials.  
At about the same level of progress as red grapes, cranberries are the furthest  
advanced among berries in the health claims research pyramid.

*Take for example the rich content of  
**proanthocyanidins** in cranberries*

Proanthocyanidins from cranberries are well on their way through clinical trials to obtain health claim status, but have not yet been proved with sufficient science to say that a specific effect is certain.

*Also note:*

***the majority of clinical trials FAIL,***  
*meaning there is no guarantee for either cranberries  
or red grapes to be  
granted a health claim in the near future.*

*How did cranberries get to this lofty position in health research?*

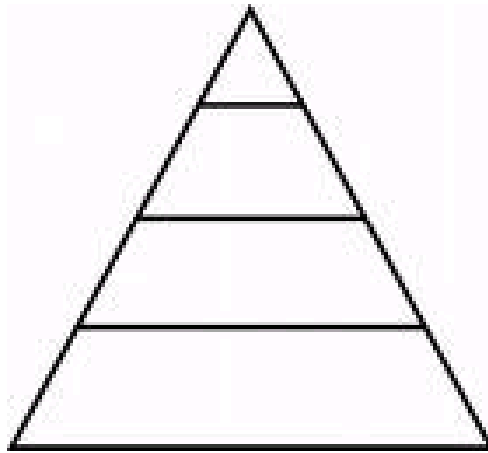
Cranberry proanthocyanidins have been called a dietary "antioxidant", but this term - although well-defined in test tube experiments - has not been proved for any dietary agent as effective with certainty in the human body except for vitamins A-C-E.

This was a topic of a recent essay in the Berry Doctor's Journal

[click here to read it](#)

## *A Health Claims Research Pyramid*

Let's consider 4 steps *from bottom to top* through a pyramid.



Use the pyramid as a visual for the steps of science -- from bottom going up -- required to reach health claim status.

At the bottom is **step 1**, "in vitro" discovery.

The **next step up, 2**, is for "in vivo" animal research.

The **3rd step up** is for "first-in-human" studies.

The **peak of the pyramid, step 4**, is where **clinical trials** are conducted. **Success in step 4 research leads to an FDA-approved health claim.**

*Where are some berries and extracts we know within the research pyramid?*

Berry or Extract	Step Position in Pyramid	Forecast Year for Reaching Step 4 at the Top	Forecast Year for Earliest Health Claim Approval
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Acai	1	2014	> 2020
Anthocyanins	3	2010	2014
Blueberry	2	2012	2020
Cranberry	4	< 2008	2012
Red grape	4	< 2008	2012
Resveratrol	4	< 2008	2012
Goji	2	2014	> 2020
Red raspberry	1	2014	> 2020
Strawberry	2	2014	> 2020

- Forecasts are estimates based on current SSA
- Forecasts apply only if berry or its phytochemicals prove of positive benefit in successful clinical trials

## *Significant scientific agreement*

(click on the title to link to the complete FDA document)

The FDA has prepared a document that lays out requirements for manufacturers seeking a health claim for a product -- it's called 'SSA' for significant scientific agreement.

SSA is a comprehensive, rigorous process that qualifies only the best new health products for clinical trials and health claim petitions. All others not meeting SSA are destined to flop and live their market exposure with no credible message about why anyone would want to buy them.

The FDA's purpose in SSA is to guard the general consumer from misinformation... or, in other words, to assure science-based truths. Anyone who follows the natural products industry would know *how rare* scientific accuracy is in product marketing.

This SSA document is also useful to those manufacturers designing studies to support health claim petitions. It's better to apply SSA at the beginning because derailment can occur early, allowing manufacturers to save expenses and 'kill' a product candidate before investment costs rise.



The common red grape (*Vitis vinifera* spp.), full of anthocyanins and resveratrol well along in the research pyramid at step 4 (clinical trials). In other words, these polyphenols are **in the 'SSA-building' phase of product development** and possible approval as genuine nutrients.

SSA means that

- the validity of the relationship is not likely to be reversed by new and evolving science,
- the science relies upon a body of sound and relevant scientific data

## Reviewing SSA

- have studies appropriately specified and measured the substance that is the subject of the claim?
- have studies appropriately *specified and measured the disease* that is the subject of the claim?
- are any and all conclusions about the substance/disease relationship based on the totality of publicly available scientific evidence?
- does the evidence shows consistency across different studies and among different researchers and permit the key determination of whether a change in the dietary intake of the substance will result in a change in a disease endpoint?

An example of **insufficient SSA**: the invalid claim that dietary polyphenols are antioxidants in the human body

- dietary antioxidant polyphenols ... anthocyanins, tannins, flavonoids, catechins, ellagic acid, and all other polyphenols we associate with health benefit from eating berries and superfruits *have not* achieved SSA, are not approved with health claims, and are not deemed as valid "nutrients"

Read [Part 2 of this link here to see the FDA guidance](#) which says

- claiming a product is an antioxidant source means it has nutrient status confirmed by SSA
- making an antioxidant statement on a product label or in marketing literature means the product or its contents have been approved through SSA as a nutrient defined with a **Reference Daily Intake** value
- a product or extract with granted nutrient designation must be proved by SSA to have antioxidant activity in the human body (must be *physiologically* active)
- it must also be proved to a) absorb from the gastrointestinal tract, b) participate in physiological, biochemical, or cellular processes that inactivate free radicals or c) prevent free radical-initiated chemical reactions in the human body

Other than vitamins A, C and E, no dietary substance -- certainly no polyphenol -- has achieved enough SSA for physiological antioxidant status.

Being objective in advertising, manufacturers would have to provide proof that antioxidants have physiological meaning in the human body.

*As they do not yet have this status*

*based on current science,  
marketing of the word 'antioxidant'  
on consumer products is not acceptable.*

*Think of how many products you know that  
use this specific marketing term anyway...*

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