

Are Naturals Necessarily Better? February 2022

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## Concept of Natural Only Defined in the Context of Flavoring Agents

21CFR101.22(a)(3) The term *natural flavor* or *natural flavoring* means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. **Natural** flavors include the **natural** essence or extractives obtained from plants listed in 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in 172.510 of this chapter.

### Concept of Natural Only Defined in the Context of Flavoring Agents

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  - spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material,
  - meat, seafood, poultry, eggs, dairy products, or fermentation products thereof,
- whose significant function in food is flavoring rather than nutritional.

21CFR101.22(a)(3)

#### Concept of Natural

Strict Rules of Use Apply – Otherwise "misleading"

21CFR101.22(I)(ii) If none of the **natural** flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

Exception: Cinnamon bark vs addition of Cinnamic acid

The same standard for colors – if the color is not characteristic of the product, a statement must be made to the effect that color was added.

Exception: Milk vs Chocolate Milk

No Exception: Lemonade vs Pink Lemonade (beet juice)

#### The Concept of Natural

FDA: "What is the meaning of 'natural' on the label of food?"

- From a food science perspective, it is difficult to define a food product that is 'natural' because the food has probably been processed and is no longer the product of the earth.
- That said, FDA has not developed a definition for use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.

http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm

#### What is Natural and What Is Not?

| Í |   | Substance   |
|---|---|---|
| ✓ |   | Ethanol made from natural gas?  |
| ✓ | ✓ | Vanilla (vanillin) not extracted from vanilla beans, but made from wood lignin?                   |
| ✓ |   | Vanilla produced by fermentation?   |
|   | ✓ | "Processed Flavors" e.g., chicken or beef flavor produced from acid hydrolysis of plant material? |
| ✓ |   | Canola oil produced by genetically modified rape seed?  |
| ✓ |   | Papaya  |
| ✓ |   | Corn  |
| ✓ |   | Salmon?   |
| ✓ |   | Pink lemonade   |
|   | ✓ | Chocolate milk  |

#### What is a Natural in the EU?

#### What is food?

#### **Article 2 - Definition of "food"**

For the purposes of this Regulation, "food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. "Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC. "Food" shall not include:

- Feed, live animals, plants prior to harvesting
- Medicinal products, cosmetics, tobacco products
- Narcotic or psychotropic substances
- Residues and contaminants.

EC 178/2002

### What is a Natural? Codex defines "natural" for flavors

- **2.2.2 Natural flavouring complexes** are preparations that contain flavoring substances obtained by
- physical processes that may result in unavoidable but unintentional changes in the chemical structure of the flavouring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material of plant or animal origin.
- Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, torrefaction (roasting) and fermentation).
- Natural flavouring complexes include the essential oil, essence, or extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis.

**GUIDELINES FOR THE USE OF FLAVOURINGS CAC/GL 66-2008 (2.2.2)** 

### Are Naturals Safe?



#### Mistaken Identities – Can you tell the difference?

Cimicifuga racemosa

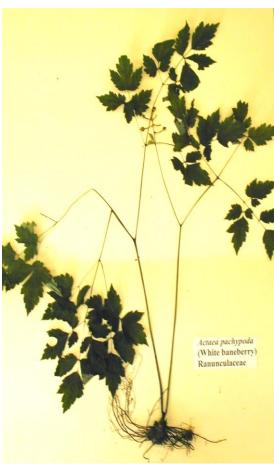
Black Cohosh

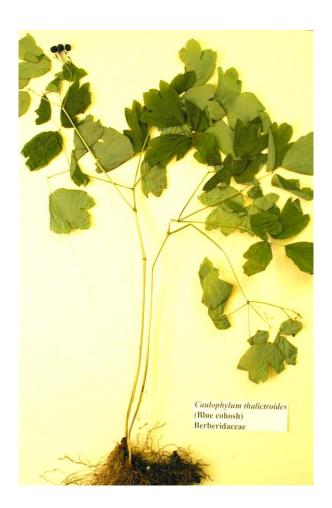
Actea pachypoda White Cohosh

Caulophyllum thalictroides

Blue Cohosh







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#### Aristolochic acid



#### Are Naturals Safe?

- Glycyrrhizic acid in licorice
- Goiterogens in Brassica
- Glycoalkaoids in potato, tomato, etc.
- Phototoxins in coldpressed oils of citrus

- Tomatine in tomatoes
- Cucurbitacin in zucchini, cucumbers, squash, etc

#### Are Naturals Safe?

Lists of approved naturals – latest vetting in late 1970's

- 21 CFR 172.510
- 21 CFR 182.10
- 21 CFR 182.20
- 21 CFR 182.40
- 21 CFR 182.50

### Influences on the Composition of Naturals Factors influencing conc. of constituents

- Commercially grown or wild botanical source
  - Similar appearing species in the same genus
  - Similar appearing plants and trash
- Variety and cultivar
- Geographical sources and growth conditions
  - Sunlight
  - Soil and nutrients
  - Moisture
  - Pests & Pesticides

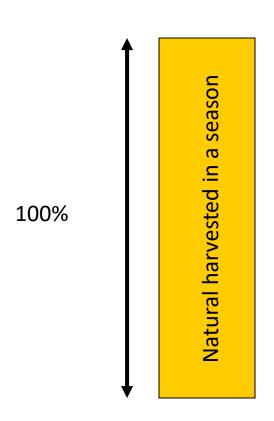
### Influences on the Composition of NFC Factors influencing conc. of constituents

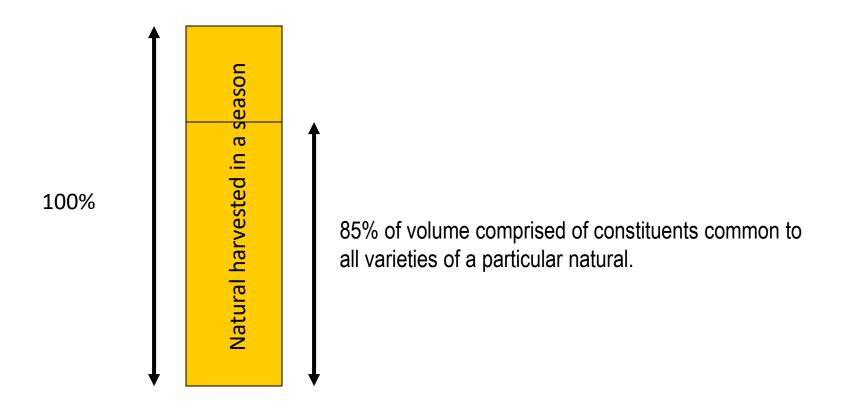
- Harvesting time (of day/season) (plants are very dynamic)
- Harvesting processes
  - Harvested and immediately extracted?
  - Post-harvest exposure to heat, humidity and insects?
- Commercially used plant parts (e.g., leaves vs. roots)
- Degree of plant maturity
- Method of isolation and inherent variability of processes

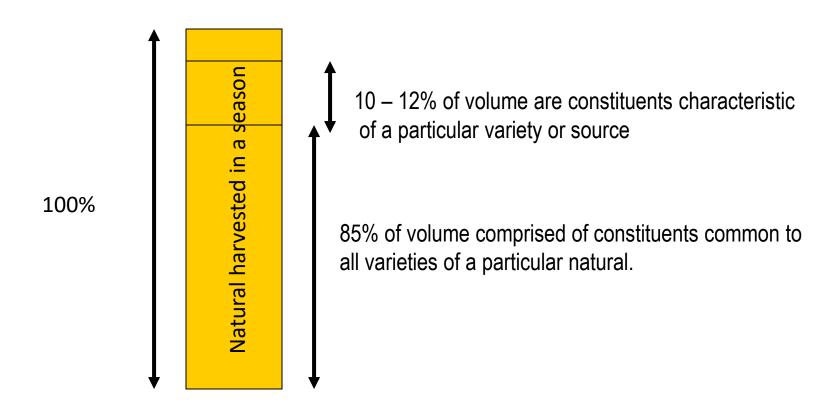
(Many preparations are variable in content)

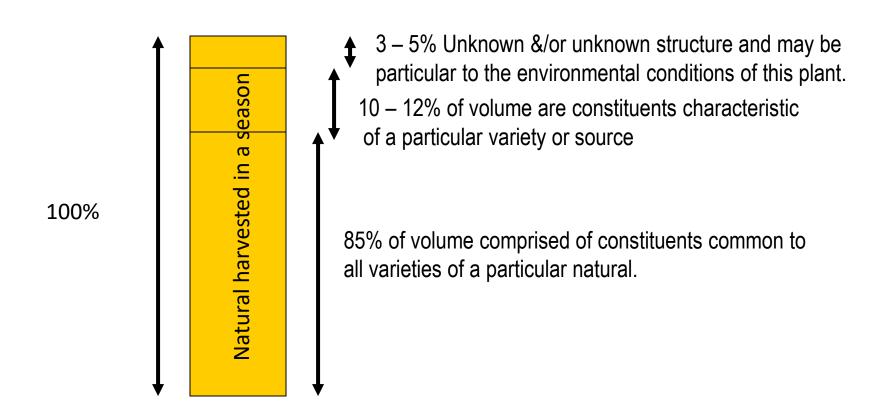
### Influences on the Composition of Naturals Factors influencing conc. of constituents

- Economic adulteration
  - Addition of marker substances
  - Natural vs. synthetic
    - Prunus spp. vs. benzaldehyde
    - Corn mint oil (Mentha arvensis L.) or Peppermint oil (Mentha piperita) vs. menthol
    - Wintergreen oil (Gaultheria procumbens L.) vs. methyl salicylate
    - Vanilla extract and vanillin
    - "Natural" vanillin
    - Honey and maple syrup vs. sugar water and flavors
- Illegal substances antibiotics in honey









### Are Naturals Safe?

