Overview

• What is activated charcoal?
• How are food ingredients regulated?
  – Food additives, color additives, GRAS, dietary ingredients
• What is the regulatory status of activated charcoal?

www.fda.gov
What is activated charcoal?

- Vegetable ash, vegetable carbon, vegetable black, activated carbon...
- **E153**: “Vegetable carbon is produced by the carbonization of vegetable material such as wood, cellulose residues, peat and coconut and other shells...”
- High temperature processing with steam
- Finely milled
- Highly adsorptive
How is activated charcoal used?

- Medicinal use to treat poisonings and overdoses
- Environmental uses to filter water, purify air
- Historical uses in cheesemaking
  - pH control agent/acidity regulator
  - Preservation barrier
  - Cheese layer separation
How is activated charcoal marketed?

- A “detox”
  - Beverages
  - Capsules
- Skin cleanser
- Pillow cases

Global market projected to be $6.2 billion by 2022
THE WALL STREET JOURNAL.

JAPAN REAL TIME

Popular Burger King Japan Offering Back, Black

By Jun Hongo

Sep 11, 2014 3:45 pm JST

Press Release

~あの黒バーガーおがプレミアムに進化~
『KURO Pearl』『KURO Diamond』
9月19日(金)より期間限定で発売!

株式会社バーガーキング・ジャパン

BKJは、2012年に“非常識”をコンセプトに今までのファストフード業界の常識を覆す、「KUROハンバーグ」を使用した“黒バーガー”を初めて発売し、その年の日本におけるBKで発売した新商品の中で最多の販売件数を記録するなど、大変ご好評をいただきました。

そして、2014年は、この“黒バーガー”をプレミアムに進化させ、選ばれる装飾をプラスして、“二つの非常識”をコンセプトとした『KURO Pearl』『KURO Diamond』を発売いたします。

『KURO Pearl』『KURO Diamond』の最大の特徴は、従来の黒を追求して新たに開発した具材に、ブラックペッパーを

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In the United States...

Ice cream that tastes like ash is the summer's latest food craze

Top 10 Food and Restaurant Trends of 2017
Forbes - Nov 29, 2017
Bret Thorn is Senior Food & Beverage Editor of Nation's Restaurant News with responsibility ... Activated charcoal turns just about any food into something highly ...
Charcoal Food Festival
San Francisco, CA, July 2018

“...come taste the dark side...”
What is the regulatory status of activated charcoal?

Is it permitted in food?

It depends....what is its intended use in food?
Definition of Food Additive (FD&C Act Sections 201(s) and 409)

- Any substance that is reasonably expected to become a component of food, except...
  - Ingredients whose use is Generally Recognized As Safe (GRAS)
  - Color additives
  - Dietary ingredients in dietary supplements
  - Prior sanctioned ingredients (substance whose use was approved by FDA or USDA prior to 1958)
  - Pesticide chemicals or pesticide chemical residue (EPA)
  - Animal drugs that may remain in food
  - Inherent components of the food
  - Contaminants not added intentionally to food

- Requires FDA premarket review and approval via petition process
  - Approval results in a regulation listed in Title 21 Code of Federal Regulations (21 CFR)
A dietary supplement contains one or more dietary ingredients:

- Vitamins
- Minerals
- Herbs or other botanical
- Amino acids
- Dietary substances used to supplement the diet by increasing total dietary intake
  - A concentrate, metabolite, constituent, or extract of a dietary ingredient

Not intended to treat diseases

FDA premarket review required only for “new” dietary ingredients via a notification program

- Dietary ingredients not sold in supplements before October 15, 1994
Food Additive Exemption - **GRAS**
(FD&C Act Section 201(s))

- The **use** of the ingredient is generally recognized as safe (GRAS), not the ingredient itself
- GRAS status requires
  - Scientific consensus by qualified experts that the use is safe
  - Based on scientific procedures (e.g., published data) or a history of common use in food before 1958
- Must meet same safety standard as food additives, but FDA premarket review and approval is **not** required
- Voluntary GRAS notification program

**FDA safety standard (21 CFR 170.3(i))**:  
“...there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use...”
Food Additive Exemption – **Color Additives**  
(FD&C Act Sections 201(t) and 721)

- A dye, pigment, or other substance that is capable of imparting color to a food, drug, cosmetic or to the human body
- Requires FDA premarket review and approval via petition process; listing in 21 CFR
  - Uses cannot be GRAS
- **Possible exemption**: if a substance is used for a purpose other than coloring and any color imparted is unimportant to the appearance, value, marketability, or consumer acceptance (21 CFR 70.3(g))
Example: Tomato Lycopene

- Synthetic lycopene
- GRAS for use as an ingredient in specific foods.
- FDA had no questions; noted some uses may require a color additive listing.

GRAS Notice #119 (2003)

- 21 CFR 73.585 Tomato lycopene extract/concentrate
- May be safely used for coloring foods generally in amounts consistent with GMP
- Petition approved by FDA

Color Additive Petition 1C0273 (2005)
What is the regulatory status of activated charcoal in food in the U.S.?

- GRAS as a processing aid only
  - Based on 1981 report by Select Committee on GRAS Substances (SCOGS)
    - Purification of water and various foods
    - Decolorization and clarification of wine
- Historical uses in cheesemaking
  - Some uses could be GRAS (see 21 CFR 70.3(g))
  - No GRAS notices submitted to FDA
What is the regulatory status of activated charcoal in food in the U.S.?

• Not considered a valid dietary ingredient
• No food additive or color additive regulation
• FDA’s current thinking summarized in “Guidance for Industry: Colored Sea Salt”
  
  • If used to impart color, it is an unapproved color additive
  • Food is adulterated under section 402(c) FD&C Act
Safety concerns?

Charcoal Food Trend is Lit, But Is It Safe?
August 10, 2018
AP NEWS

Charcoal is trendy ingredient at Twin Cities restaurants, but comes with risk
Welcome to the dark side of cocktails and lattes.
By Amelia Raymond
Star Tribune
JUNE 15, 2018 — 11:53 AM

Doctors Warn Activated Charcoal Food Craze Might Not Be Healthy
By Stephanie Stahl
March 8, 2019 at 6:46 pm
Filed Under: HealthWatch, Local TV
Safety concerns?

• Unknown source material
  – Wood, bone, coconut shells, other materials?
  – Presence of heavy metals, other impurities?
• Potential for the presence of polycyclic aromatic hydrocarbons (PAHs)
  – Created during combustion process
  – Known carcinogens
• Particle size distribution; nano?
• Unknown effects of chronic consumption

FDA safety standard (21 CFR 170.3(i)):
“...there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use...”
Take-aways

• The intended use of activated charcoal determines its regulatory status
  – Certain uses may be GRAS
• Activated charcoal is not an approved color additive
  – There is no listing for activated charcoal in 21 CFR
  – Foods containing activated charcoal as an unapproved color additive may be deemed adulterated (section 402(c) FD&C Act)
• Case-by-case assessment if use meets the definition of a color additive, based on 21 CFR 70.3(g)
• End of a trend?
  – Recent media reports questioning safety
  – Increased enforcement (e.g., NYC, Portland)