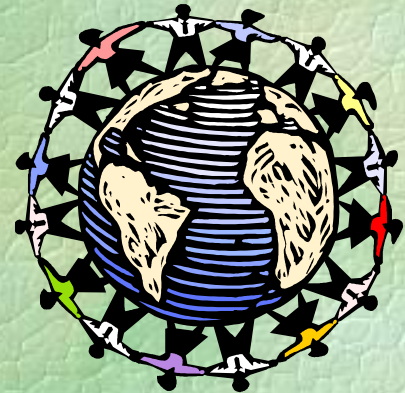


Regulatory Considerations for New Varieties in a Global Market

Kristen Carlson

Florida Citrus Processors Assn.



A short history: Once upon a time in citruslandia...

Regulation was thought to be the way to tame the market, keep consumers from bad experiences and stop cheaters and adulteration.



REGULATE!

1949 Florida Citrus Commission- Citrus Code of 1949- standards for orange juice products were adopted.

CHAPTER 601. FLORIDA CITRUS COMMISSION. Jan. 20.

name and address, the words "Citrus Adm'd", the words "made in a factory", the words "Product of the U. S. A.", the grade and number of the fruit, and a most ample or descriptive design indicating the origin of the fruit or the facility in which it was grown, may be displayed in any or numerous ways, the design in this instance to serve as the seal or mark on the of the Commission office. In addition, the word "The Commission of Citrus" may be used in any or numerous ways, together with a brief information statement, in design and to avoid any mark such as design may be used in the same manner and in a way beyond the control of the Commission office. In addition, the words of the design in the brand name and design's name and address appear on the design of the of the Commission office.

Mark which may appear on any other design, including the design of the brand name and design's name and address, may be used in any or numerous ways, together with a brief information statement, in design and to avoid any mark such as design may be used in the same manner and in a way beyond the control of the Commission office.

10. The design of the brand name and design's name and address, may be used in any or numerous ways, together with a brief information statement, in design and to avoid any mark such as design may be used in the same manner and in a way beyond the control of the Commission office.

11. The design of the brand name and design's name and address, may be used in any or numerous ways, together with a brief information statement, in design and to avoid any mark such as design may be used in the same manner and in a way beyond the control of the Commission office.

12. The design of the brand name and design's name and address, may be used in any or numerous ways, together with a brief information statement, in design and to avoid any mark such as design may be used in the same manner and in a way beyond the control of the Commission office.

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14. The design of the brand name and design's name and address, may be used in any or numerous ways, together with a brief information statement, in design and to avoid any mark such as design may be used in the same manner and in a way beyond the control of the Commission office.

Size	Feet	Area	Volume	Cost
100	100	100	100	100
100	100	100	100	100
100	100	100	100	100
100	100	100	100	100
100	100	100	100	100
100	100	100	100	100
100	100	100	100	100
100	100	100	100	100
100	100	100	100	100

When grapes are shipped in this box, the size, weight, volume and moisture must be as specified in the U. S. Grade Standards for Florida Grapes.

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- oranges are defined to be *Citrus sinensis*
- Orange juice is made from oranges. Chapter 601 Fla. Stat.



1949-50

Seated: Jeff Flake, R. A. Fender, Dodge Taylor, Chairman, J. B. Prevatt, O. C. Minton. Standing: John Snively, Jr., J. R. McDonald, J. B. Stephens, W. E. Bishop, Dan L. McKinnon, L. S. Andrews, Jr., Tom Turnbull.

FCOJ and other forms of juice were proliferating; tangerine juice was being sold as orange juice. Per FDA, housewives were confused! ; and non-Florida juice plants did not follow Florida standards

**The
problem--
no juice
regulation
outside of
Florida!**

Florida



What to do? What to do?

Here's your
10¢ COUPON
good on any brand of
frozen orange juice



Delicious Florida orange juice gives you the natural Vitamin C and energy your body thirsts for every morning. Remember, your body can't store Vitamin C.

Wonderfully convenient! Each 6-ounce can makes 24 ounces—the 12-ounce can makes 48 ounces of delicious Florida orange juice.

SAVE!

Redeem this coupon
on any brand
of your choice—
TODAY!

© Florida Citrus Commission, Lakeland, Florida, 1962

REDEEM THIS COUPON TODAY

10¢ WORTH 10¢ ON 4 (or more) CANS

Four 6-oz. cans or two 12-oz. cans
ANY BRAND OF FRESH-FROZEN ORANGE JUICE FROM FLORIDA

To the dealer: You will be reimbursed 10¢ plus 2¢ handling allowance. A. C. Nielsen Co. will redeem this when mailed to Florida Orange Juice Company, Box 1382, Clinton, Iowa, in Canada, Box 9, Don Mills, Ontario before April 15, 1964. Coupons received thereafter void. Coupon void if torn, prohibited, or restricted by law. Cash value: 1¢ of 10.
Fraud clause: Any other application of this coupon constitutes fraud. Invoicing proving purchase, within the last 90 days of sufficient stock to cover coupons presented for redemption must be made available upon request.

COUPON EXPIRES DECEMBER 31, 1963

fresh
out of its
skin!



**The truest, richest juice ever frozen -
with twice as much fresh orange essence!**

New Libby's has caught the natural flavor other brands have been chasing! Remember the last sweet fragrance of oranges being squeezed? Remember that fresh juice taste? No brand ever had it—till now, till Libby's! You see, normally when orange juice is concentrated, some of the finest orange essence is lost. To try and make up for it, most orange juice people just add back regular juice. But now Libby's has discovered how to recover and add back orange essence. That's the factory, fragrant pack of orange juice. And

they add it till Libby's has twice as much fresh orange essence as other brands! Only Libby's makes orange juice this way. Pour some Libby's tomorrow. Then close your eyes and you'll think you're in orange country.  Introductory offer: Buy 12 cans—get 1 free! Send us the Libby's "NEW" from 4 six-ounce cans of Libby's Orange Juice Concentrate. We'll send you 24¢ that's more than the cost of 1 can! Send to: Libby's Orange Juice, Box 243, Chicago 22, Illinois. This offer expires July 31, 1962.

NEW
FROM LIBBY'S

Issued in Washington, D.C., on October 4, 1963.

H. B. HELSTROM,
Acting Chief,
Airspace Utilization Division.

[F.R. Doc. 63-10771; Filed, Oct. 10, 1963;
8:48 a.m.]

[Airspace Docket No. 63-WE-100]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS (NEW)

Alteration of Control Zone and Control Area Extension

The purpose of these amendments to Part 71 (New) of the Federal Aviation Regulations is to alter the description of the Cheyenne, Wyo., control zone and control area extension.

The Cheyenne control zone and control area extension are presently designated, in part, with reference to the Cheyenne radio range. The Federal Aviation Agency has converted this facility to a radio beacon. The action taken herein reflects this conversion in the description of the Cheyenne control zone and control area extension. Controlled airspace requirements for this area will be further reviewed at a later date under the CAR Amendments 60-27/60-29 implementation program.

Since these amendments are editorial in nature and impose no additional burden on any person, notice and public procedure hereon are unnecessary.

In consideration of the foregoing, the following actions are taken:

1. In § 71.171 (27 F.R. 220-91, November 10, 1962), the Cheyenne, Wyo., control zone is amended to read:

Cheyenne, Wyo.

Within a 5-mile radius of the Cheyenne Municipal Airport (latitude 41°09'26" N., longitude 104°48'26" W.); within 2 miles of the Cheyenne radio range from the Chey-

(Sec. 307(a), 72 Stat. 740; 49 U.S.C. 1348)

Issued in Washington, D.C., on October 4, 1963.

H. B. HELSTROM,
Acting Chief,
Airspace Utilization Division.

[F.R. Doc. 63-10772; Filed, Oct. 10, 1963;
8:46 a.m.]

Title 16—COMMERCIAL PRACTICES

Chapter I—Federal Trade Commission

SUBCHAPTER D—TRADE REGULATION RULES

PART 400—ADVERTISING AND LABELING AS TO SIZE OF SLEEPING BAGS

The Federal Trade Commission, pursuant to the Federal Trade Commission Act, as amended, 15 U.S.C. 41, et seq., and the provisions of §§ 1.61 through 1.71 of the Commission's rules of practice, procedures and organization, 27 F.R. 4611-12 (May 1962), has conducted a proceeding for the promulgation of a Trade Regulation Rule regarding deception resulting from advertising and labeling of the size of sleeping bags. Notice of this proceeding appeared in the Federal Register on February 19, and June 7, 1963 as proposed § 320.1 (28 F.R. 1361, 5619). In this rule-making proceeding the Commission has considered its findings and decision in Outdoor Supply Company, Inc., Docket 7482, 67 FTC 361 (1960), its orders to cease and desist entered pursuant to consent agreements in other adjudicative proceedings, the views expressed by interested parties in this proceeding, and all other relevant matters of fact, law, policy and discretion.

§ 400.1 The rule.

lation rule, its findings and determination that in connection with the sale or offering for sale of sleeping bags, any representation of the "cut size" or the dimensions of materials used in the construction of sleeping bags, in advertising, labeling, marking or otherwise, constitutes an unfair method of competition and an unfair and deceptive act or practice, unless—

(1) The dimensions of the cut size are accurate measurements of the yard goods used in construction of the sleeping bags; and

(2) Such "cut size" dimensions are accompanied by the words "cut size"; and

(3) The "cut size" is accompanied by a clear and conspicuous disclosure of the length and width of the finished products and by an explanation that such dimensions constitute the finished size.

Example. An example of proper size marking when the product has a finished size of 33" x 68" and a cut size of 30" x 72", and disclosure is made of the cut size, is—
Finished size 33" x 68"; cut size 30" x 72".

(38 Stat. 717, as amended; 15 U.S.C. 41-58)

This rule becomes effective on November 12, 1963.

Adopted: September 18, 1963.

By the Commission.

[SEAL] JOSEPH W. SHEA,
Secretary.

[F.R. Doc. 63-10765; Filed, Oct. 10, 1963;
8:46 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS [Docket No. FDC-70]

PART 27—CANNED FRUITS AND CANNED FRUIT JUICES; DEFINI-

**REGULATE!! 1963- fix it
with new standards of
identity; Citrus sinensis
required by Federal law.**

FDA Standards of Identity

- Limited **orange juice** to *citrus sinensis* sweet orange 21 CFR146.135
- FCOJ- up to 10% from *citrus reticulata* or *citrus reticulata* hybrids and 5% *citrus aurantium* (sour orange)
- Pasteurized Orange Juice -10% from *citrus reticulata* or *citrus reticulata* hybrids
- Orange Juice from Concentrate (same as above)
- Canned OJ- up to 10% *citrus reticulata*

1980s Florida saw back to back freezes, supply decreased/imports arrived into the U.S.



With freezes, Florida has a supply problem and growers worry about replanting. Plant breeders to the rescue. An early maturing tree could help freeze problems except growers won't plant/processors won't buy if the fruit is not citrus sinensis.

- Organoleptic testing showed it's juice tasted significantly like juice from *citrus sinensis*
- Early maturing to reduce risk of freeze damage

**AMBERSWEET WAS “ORANGE
LIKE”**

The Ambersweet

$\frac{1}{2}$ *citrus sinensis*

$\times \frac{3}{8}$ *citrus*

reticulata $\times \frac{1}{8}$

citrus paradisi

*Amended by
name into federal
standard of ID for
orange juice 1992*

Sec. 146.135 Orange juice.

(a) Orange juice is the unfermented juice obtained from mature oranges of the species *Citrus sinensis* or of the citrus hybrid commonly called "Ambersweet" ($\frac{1}{2}$ *Citrus sinensis* \times $\frac{3}{8}$ *Citrus reticulata* \times $\frac{1}{8}$ *Citrus paradisi* (USDA Selection:1-100-29: 1972 Whitmore Foundation Farm)). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by current good manufacturing practice) and excess pulp are removed. The juice may be chilled, but it is not frozen.

(b) The name of the food is "orange juice". The name "orange juice" may be preceded on the label by the varietal name of the oranges used, and if the oranges grew in a single State, the name of such State may be included in the name, as for example, "California Valencia orange juice".

[42 FR 14433, Mar. 15, 1977, as amended at 57 FR 57667, Dec. 7, 1992]



**In Florida, Charely, Frances and Jeanne
2003-04**

2004



CURRENT FLORIDA CITRUS SITUATION

- **Production and Tree Losses**

- ▶ **Hurricanes**

- ▶ **Diseases**

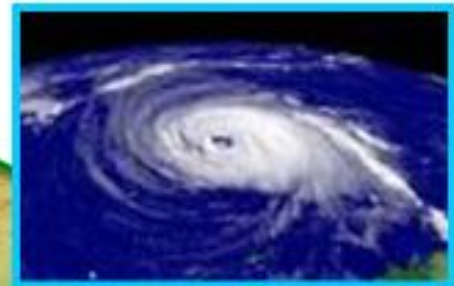
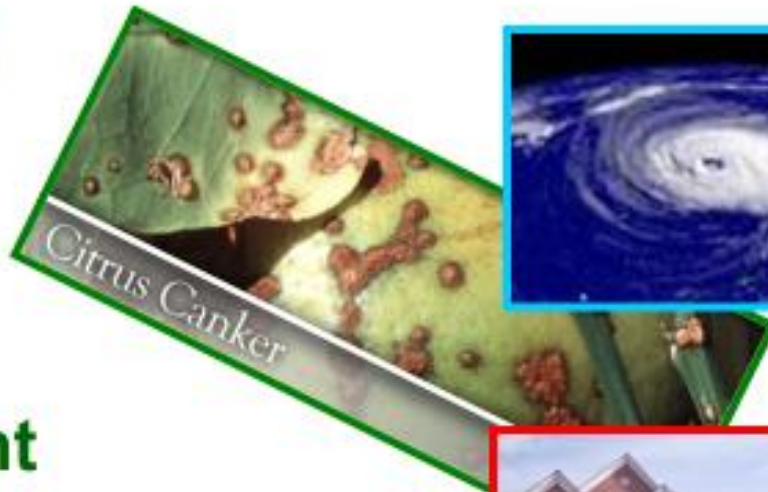
- ▶ **Canker**

- ▶ **Greening**

- ▶ **Tristeza**

- ▶ **Development**

- **Consumption Falling**





2008 citrus greening/HLB takes over

Kills trees and the juice of
symptomatic trees does not taste so
great

**Researchers work on HLB &
ways to repel ACP with no luck—
-Can breeders develop HLB
tolerant plants?**

- **Conventional breeding of inter-specific hybrids**
- **Genome editing**

Aerial view of 5-51-2 surrounded by Early Pride



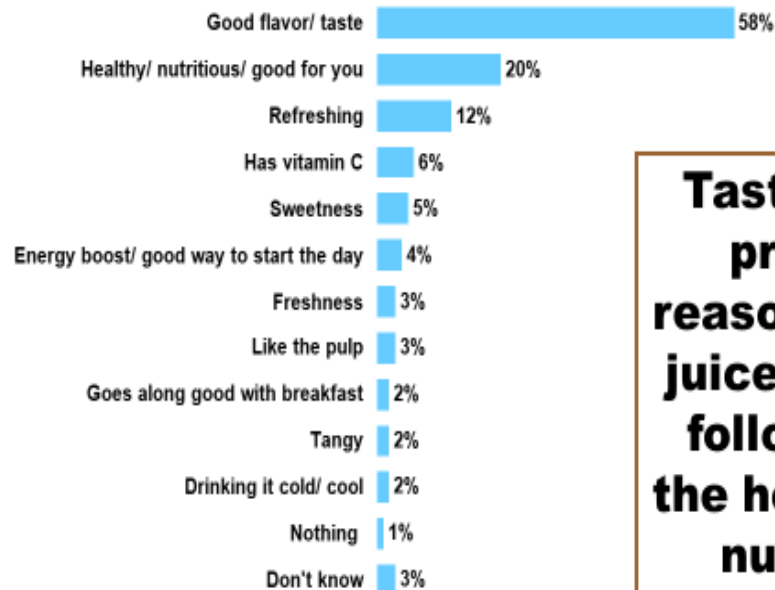
HLB-tolerance in some but not all mandarin types.

BUT there is another major source of tolerance...

HLB tolerance is great-- but taste is, by far, the main reason consumers like orange juice— so breeders must also breed new plants for flavor

Reasons for Liking Orange Juice

Source: Orange Juice Segmentation Study, IPSOS. Nov 2009.



Note: Only mentions of 2% or more shown.

Base: All respondents (n=3,080)

Q.23 What do you like most about drinking orange juice?

Taste is the primary reason orange juice is liked, followed by the health and nutrition benefits.

Through breeding new plant material –HLB tolerant trees with “orange like” fruit could solve the HLB problem- except growers won’t plant and processors won’t buy because..

Inter-specific hybrids might show
HLB tolerance but they would
not be *citrus sinensis*

Eureka!

What if we say that *citrus sinensis* is not a true species?

That *citrus sinensis* is actually itself a hybrid comprised of 60% citrus reticulata x 40% pummello

We can say that because it is true!

Careful comparative analyses reveal the true nature of the structural genomics of various kinds of citrus. Defining a “sweet orange” by regulation, using the old and invalid species concepts, is meaningless in the face of what genome sequencing of citrus cultivar types has revealed. Chemical parameters and sensory analysis of the juice products makes much more sense for product classifications, than faulty taxonomy. Fred Gmitter’s opinion 4/19/19.

Say, let’s change the archaic standards of identity!

“Orange juice is the unfermented juice obtained from mature fruit of the sweet orange (conforming to the genotype known as *Citrus sinensis*) or from fruit with an ancestral interspecific pedigree similar to that of the sweet orange and with color, flavor and organoleptic properties typical of sweet orange”

**EXAMPLE OF A NEW
STANDARD FOR OJ-CAN WE
DO THAT?**

2019 FDA deleted the
cherry pie standard

FDA does not favor
opening up their rules to
make little changes. (like
reducing 10.5 Brix NFC)

Many fruit juices do not
have standards of identity
– should we delete rather
than amend?



How Many Cherries in Frozen Pie? FDA May Soon Drop Rules

Associated Press • April 19, 2019, at 6:32 p.m.

By CANDICE CHOI, AP Food &
Health Writer

NEW YORK (AP) — President Donald Trump may soon be able to claim a sweet victory for his deregulation push, with officials preparing to get rid of the decades-

9/27/19 FDA is taking testimony to review FDA Standards of identity to promote nutrition and innovation— is there an opening?

Center for Food Safety and Applied Nutrition Constituent Update

FDA Announces Public Meeting to Discuss Modernizing Food Standards of Identity August 28, 2019

The U.S. Food and Drug Administration today announced it will hold a [public meeting](#) on September 27, 2019, to give interested parties an opportunity to discuss FDA's effort to modernize food standards of identity and to provide information about changes the FDA could make to existing standards of identity. FDA is particularly interested in changes that could be made across categories of standardized foods, often referred to as horizontal changes, to provide flexibility for manufacturers to develop healthier foods. FDA is particularly interested in changes that could be made across categories of standardized foods, often referred to as horizontal changes, to provide flexibility for manufacturers to develop healthier foods and to facilitate innovation.

The initiative is part of the agency's comprehensive, multi-year [Nutrition Innovation Strategy](#) (NIS), which is designed to encourage industry innovation to improve the nutrition and healthfulness of food. As part of the NIS, FDA is seeking to modernize food standards of identity in a manner that will: (1) protect consumers against economic adulteration; (2) maintain the basic nature, essential characteristics and nutritional integrity of food; and (3) promote industry innovation and provide flexibility to encourage manufacturers to produce healthier foods.

Because the agency issued many standards of identity decades ago, FDA and many stakeholders are concerned that some standards are out of date and may impede innovation. As consumers continue to seek more nutritious food options, FDA wants to ensure that standards of identity, or requirements outlining the content and production of certain food products, meet these expectations. During a [2018 public meeting](#) on FDA's Nutrition Innovation Strategy, many participants expressed general support for FDA exploring modernization options that could permit changes across all standards of identity, or broad categories of standards, to facilitate innovation and flexibility to reformulate products to produce more nutritious foods. FDA is seeking input about horizontal changes that may provide manufacturers with additional flexibility to use, for example, new technologies and new or novel ingredients without impacting the basic nature and essential characteristics of standardized foods.

The September 27th meeting will be held from 8:30 a.m. until 5:00 p.m. at the Hilton Washington DC/Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852. The meeting will include introductory presentations, a panel presentation, oral comments by attendees, as well as breakout sessions. Public meeting attendees are encouraged to [register online](#) to attend the meeting in person and via live webcast.

For questions about registering for the meeting or to register by phone, contact Mark Gifford, SIDEM, 1775 Eye Street, NW, Suite 1150, Washington, DC 20006, 240-393-4496, EventSupport@Sidemgroup.com.

For general questions about the meeting or to request special accommodations due to a disability, contact Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, phone: 240-402-1731, email: Juanita.Yates@fda.hhs.gov.

For more information about the meeting, as well as instructions on registration and requesting to make an oral presentation, see the [Federal Register Notice](#) announcing the meeting and the [meeting page](#).

Important Dates to Remember:

- Request to make an oral comment: September 12, 2019
- Request special accommodations due to disability: September 12, 2019
- Advanced registration closing date: September 20, 2019
- Public meeting: September 27, 2019, 8:30 a.m. to 5:00 p.m.
- Deadline to submit written/electronic comments: November 12, 2019

Considering Hybrids for Processing

- This ABSOLUTELY must be an industry-driven process, and we are hoping that this information stimulates discussion
- Clearly, implementation requires substantial research including:
 - production
 - quality parameters
 - acceptable maturity windows
 - transportation/handling (softer fruit?)
 - blending for uniform products
 - consumer acceptance
 - implications for international trade

The rest of the world?





CODEX ALIMENTARIUS



FAO/WHO Food Standards - Normes Alimentaires FAO/OMS - Normas Alimentarias FAO/OMS

**Codex Standard for OJ references *citrus
sinensis***

The Force and Effect of Codex Texts

- SPS Agreement references
- TBT Agreement references
- WTO uses as benchmark for national standards in settling trade disputes
- WTO members commitment to adopt?
- Default standards for industry

AIJN Code of Practice

- For 18 fruits, AIJN has created a detailed description of quality and composition
- Juices must meet these standards in the EU
- Has become a standard for international trade
- Only looks at juices that go to EU. Authentic juices that didn't get in the database are sometimes at a trade disadvantage.
- Uses IFU, AOAC, etc methods

AIJN C.O.P. references *citrus*
sinensis

**The industry
will have to
build consensus
on which
regulatory
approach to
take.**

Amend/delete



FCPA supports the development of new plant materials that are HLB tolerant with orange juice like characteristics



Three Legs of “CHAMP” Program

- Breed plant material with HLB tolerance
- Evaluate new plant material basis HLB tolerance, juice quality and other attributes
- Make place in regulations so fruit from new trees can be able to be used; give growers confidence to plant



Conclusion

- * *Citrus sinensis* is not a species
- * Other fruits/juices not so limited
- * U.S. standards can be changed
- * Global standards may be more difficult
- * We have time while plants are being developed

Thank you.

Fcpa Members

www.fcplanet.org

