Regulatory Considerations for New Varieties in a Global Market

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

- oranges are defined to be *Citrus sinensis*
- Orange juice is made from oranges. Chapter 601 Fla. Stat.
1949-50

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!
What to do? What to do?
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 (sames 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 plantprocessors 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
½ citrus sinensis
x3/8 citrus reticulata x 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" (1/2 *Citrus sinensis* X 3/8 *Citrus reticulata* X 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".

In Florida, Charely, Frances and Jeanne
2003-04
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.
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 \textit{citrus sinensis} is not a true species?

That \textit{citrus sinensis} is actually itself a hybrid comprised of 60\% \textit{citrus reticulata} x 40\% \textit{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: 240-403-1731, 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 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