The Role of Ingredient Standards in Protecting Supply Chain Integrity

Steven Gendel
Senior Director, Food Science
Food Chemicals Codex

Agenda

- The problem
  - Threats to supply chain integrity
- The solution
  - Preserving supply chain integrity
    - How ingredient standards can help

The problem

- Complex supply chains create opportunities for adulteration and fraud

- The usual view of the supply chain is simple and linear

The problem

- Complex supply chains create opportunities for economically motivated adulteration and fraud
  - Reality is much more complex

There are many threats to supply chain integrity

Some examples

- From a 2015 news story:

  "A depot boy with the Akuafo Adamfo Cocoa Marketing Company Limited at Dadieso in the Western Region and a cocoa purchasing clerk have been imprisoned for 5 years each by a Takoradi circuit court for **adulterating the contents of sealed cocoa beans with stones**."

- From a 2017 EuroPol/Interpol report:

  "When 1 300 kg of roasted chopped hazelnuts were checked, German authorities detected **8% of admixed peanuts**. In 500 kg of hazelnut paste, up to **45% of mixed cashew nuts** were detected. In another hazelnut paste, **27% of admixed almonds** could be determined."

- From a 2008 court document:

  "the contamination was likely caused by **injections of mercury** into the vanilla beans by Indonesian farmers seeking to boost the weight of their crop yields"

There are many threats to supply chain integrity

Some more examples

- From a 2018 news story:

  "a former employee told the authorities that it had been common practice at Yi Jin King since 2016 to **mix eggs close to their sell-by date with fresh eggs** and sell them under **misleading labels**"

- From a 2017 news story:

  Police during their raids also found that the arrested accused without obtaining license and permission from Food authorities also indulged in adulterated sweet preparation and **ice creams** by using **white wash cement, artificial chemical food colours**, a release from Hyderabad Police Commissionerate said.

There are other supply chain issues

- **Beside needing to avoid fraud and adulteration, you need to know that your ingredients have the appropriate quality**
- **From the IDFA web site:**

Quality Segments

In addition, there are commonly used marketing phrases that describe ice cream products in terms of quality segments, such as "superpremium," "premium" and "economy." Several factors can contribute to a product's quality segment such as price, brand positioning, product packaging, quality of ingredients, milkfat content and the amount of overrun (air) in the product. Overrun refers to the amount of aeration the ice cream undergoes during its manufacture that keeps the mixture from becoming an inedible frozen mass. Overrun is governed by federal standards in that the finished product must not weigh less than 4.5 pounds per gallon.

There are other supply chain issues

What does ingredient quality mean?

Quality Segments

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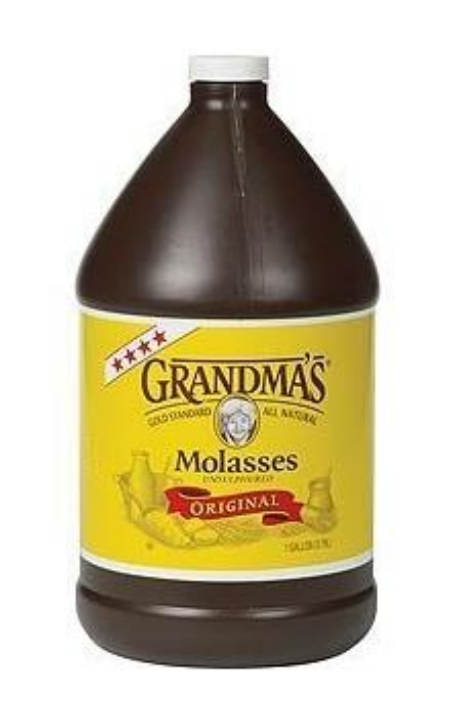
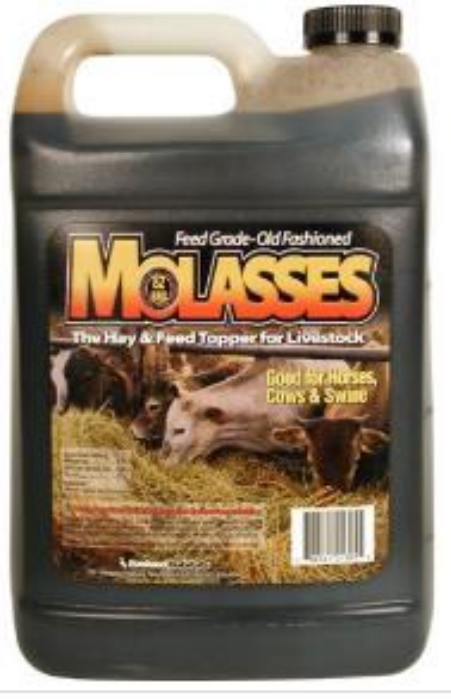
What does ingredient quality mean?

- All three are the same chemical (identity) – but clearly the appropriate level of quality (i.e., purity, grade) differs

What does ingredient quality mean?

- The availability of non food grade ingredients creates opportunities for substitution of dilution– either by accident or by malfeasance in the supply chain





- Both 1 gallon
- One sells for $25.00, the other for $15.00

The Problem - Summary

- There are multiple threats to the integrity of your supply chain
  - These threats can impact product quality and safety
  - Not to mention the viability of your business
- In the US, you can not expect help from food regulatory agencies
  - Unless the threat has direct health impact

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  - Threats to supply chain integrity
- **The solution**
  - **Preserving supply chain integrity**
    - **How ingredient standards can help**

Preserving Supply Chain Integrity

- You need to actively protect the integrity of your supply chain
  - Don’t assume anything
    - Including that what you knew yesterday is true today
- Limit trust and verify
  - Focus on actual physical ingredients
  - Records can be inaccurate, altered, or worse
  - Blockchain is of limited help
    - Garbage in, garbage out
- Transparency and traceability are not just for consumers
  - If you don’t have full view of your supply chain, can you be sure that you know your ingredients?

What does it mean to know your ingredients?

- Know what you want
- Know what you get

Knowing your ingredients

- Know what you want
  - Use rigorous purchase specifications
    - You don’t tell your label printer to use “red” and expect to get the right color, or the same color each time, you define precisely which red you want
    - You should use at least the same level of care in defining your ingredient expectations
  - Purchase specifications should include
    - Unambiguous identity
    - Expected purity
    - Limits on impurities
    - Absence of contaminants

Knowing your ingredients

- Know what you get
  - Verify that what you get is what you expect
  - Each ingredient should have
    - The correct identity
    - The expected purity
    - Limited impurities
    - No contaminants

Preserving Supply Chain Integrity

- The same ingredient properties are critical to both specification and verification
- How can you define these properties?
  - The hard way
    - Do it yourself
  - The easy way
    - Use ingredient standards

What are ingredient Standards?

- Standards tell you what an ingredient is supposed to be
- Good standards tell you how to determine whether a particular sample meets that standard
- Standards, by defining appropriate ingredient properties, allow clear communication along the supply chain
  - This clarity is essential for transparency

The anatomy of an ingredient standard

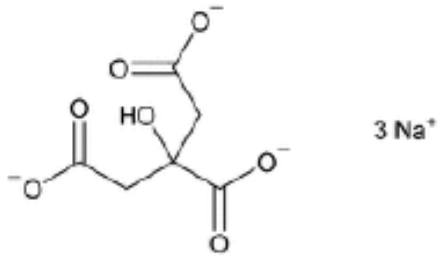
- Example - Food Chemicals Codex (FCC) standards
  - The FCC was created by the FDA and the National Institute of Medicine
  - Currently published by USP
  - >1250 standards for additives, ingredients, and other food chemicals
  - Standards are developed by expert volunteers
  - The only fully independent source of food ingredient standards

An example of a FCC standard

Sodium Citrate

Published in: FCC 11 | FCC 11 1S | FCC 11 2S
First Published: Prior to FCC 6

Trisodium Citrate



$C_6H_5Na_3O_7$
Formula wt, anhydrous 258.07
$C_6H_5Na_3O_7 \cdot 2H_2O$
Formula wt, dihydrate 294.10
INS: 331(iii)
CAS: anhydrous [68-04-2]
CAS: dihydrate [6132-04-3]
UNII: B22547B95K [trisodium citrate dihydrate]
UNII: RS7A450LGA [anhydrous trisodium citrate]

DESCRIPTION

Sodium Citrate occurs as colorless crystals or as a white, crystalline powder. It is anhydrous or contains two molecules of water of crystallization. One g of the dihydrate dissolves in 1.5 mL of water at 25° and in 0.6 mL of boiling water. It is insoluble in alcohol.

Function: Buffer; sequestrant; emulsion stabilizer; nutrient for cultured buttermilk

Packaging and Storage: Store in tight containers.

- Descriptive Information
- Including synonyms

An example of a FCC standard

IDENTIFICATION

- **Citrate, *Appendix IIIA***
  Sample solution: 50 mg/mL
  Acceptance criteria: Passes test
- **Sodium, *Appendix IIIA***
  Sample solution: 50 mg/mL
  Acceptance criteria: Passes test

ASSAY

- **Procedure**
  Sample: 350 mg

Analysis: Transfer the *Sample* into a 250-mL beaker. Add 100 mL of glacial acetic acid, stir until completely dissolved, and titrate with 0.1 N perchloric acid, using *crystal violet TS* as the indicator. Each mL of 0.1 N perchloric acid is equivalent to 8.602 mg of $C_6H_5Na_3O_7$. [**Caution**— Handle perchloric acid in an appropriate fume hood.]

Acceptance criteria: NLT 99.0% and NMT 100.5% of $C_6H_5Na_3O_7$, calculated on the anhydrous basis

- Identification tests and purity assays
- With acceptance criteria

An example of a FCC standard

IMPURITIES

Inorganic Impurities

- LEAD, *Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB*

  Sample: 5 g

  Acceptance criteria: NMT 2 mg/kg

SPECIFIC TESTS

- ALKALINITY

  Sample solution: 1 g in 20 mL of water

  Analysis: Confirm that the *Sample solution* is alkaline to litmus paper. Then, add 0.2 mL of 0.1 N sulfuric acid to the *Sample solution* and follow with one drop of *phenolphthalein TS*.

  Acceptance criteria: No pink color appears after addition of the *phenolphthalein TS*.

- WATER, *Water Determination, Appendix IIB*

  Acceptance criteria

  Anhydrous: NMT 1%

  Dihydrate: Between 10.0% and 13.0%

- Impurity and other tests

Other Ingredient Standards

- Joint Expert Committee for Food Additives (JECFA)
  - Governmental - administered by WHO and FAO
  - Standards for additives
- Codex Alimentarius
  - Governmental - administered by WHO and FAO
  - Standards for commodities
- Flavor and Extract Manufacturers Association (FEMA)
  - Industry
- ISO
  - Industry +
  - Standards for management as well as for various foods
- Government and regulatory standards

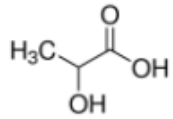
Using standards to know what you want

- Cite a standard in your purchase requirements
- Find suppliers that include a standard in their product specification

Product Specification

Product Name:
Lactic acid - 85% FCC

Product Number:	**W261106**
CAS Number:	50-21-5
MDL:	MFCD00004520
Formula:	C3H6O3
Formula Weight:	90.08 g/mol



TEST	Specification
Appearance (Color)	Colorless to Light Yellow
Appearance (Form)	Viscous Liquid
Refractive index at 20 ° C	1.423 - 1.428
Infrared spectrum	Conforms to Structure
Trace Hydrocyanic Acid 5 ppm Maximum	Pass
Titration by HCL	80.8 - 89.3 %
ChlorideTest	Pass
Miscellaneous Assay Sugars Test	Pass
Miscellaneous Assay (Citric, Oxalic, Phosphoric, Tartaric Acid)	Pass
Sulfate	≤ 0.25 %
Iron (Fe)	≤ 10.0 ppm
Residue on ignition (Ash)	≤ 0.1 %
Arsenic (As)	≤ 3 ppm
Cadmium (Cd)	≤ 1 ppm
Mercury (Hg)	≤ 1 ppm
Lead (Pb)	≤ 0.5 ppm
Expiration Date Period 5 Years	----------

Using standards to know what you get

- Why it is important to verify that what you get is what you expect
  - An example from a real supplier COA

The above information is based on the certificate of analysis received from our supplier and is not intended as a substitute for strict quality control analysis by the purchaser of this product.

- If you purchase from this company you don't know who the supplier is, who actually created the product, who handled the product along the supply chain, who did the analysis, whether the analysis was done correctly, or whether the information of the COA is actually correct

Using standards to know what you get

- Know your whole supply chain if you can
  - Know who is protecting your ingredient quality, and how are they doing it
  - Don’t believe ~~everything~~ anything that you read
- Always do some QA testing of what you receive
- Find a lab who you trust to check your ingredients for you

Using standards to know what you get

- Find a lab who you trust to check your ingredients for you
  - They need to be working for you
  - Be sure that they are ISO certified for the type of testing that you require
    - This includes participating in proficiency testing, and sharing their results
  - Agree on which standards will be used
  - Agree on which methods will be used
  - Be aware of potential EMA and include appropriate tests if they are not already part of the standard

Summary

- Supply integrity and transparency are critical for protecting your product and your business
- No one else cares as much as you do
  - Don’t assume that anyone else is looking after your interests and needs
- Today, you need to think beyond regulations
- Food ingredient standards are your best defense to protect against EMA, fraud, and miscommunication along the supply chain

An opportunity to help

- Learn more about the FCC
- Help us identify needs and priorities so that our work has the maximum benefit
- In person and via WebEx
- For more information: go to www.usp.org and search for “food stakeholder”

Thanks

Steven Gendel
Senior Director, Food Science
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steven.gendel@usp.org