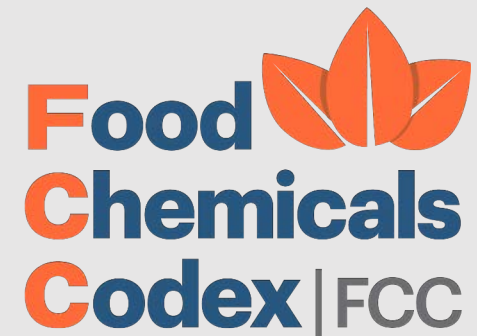# Documentary Standards and Reference Materials - Safeguarding the Supply Chain Together

Steven Gendel, PhD
Senior Director, Food Science
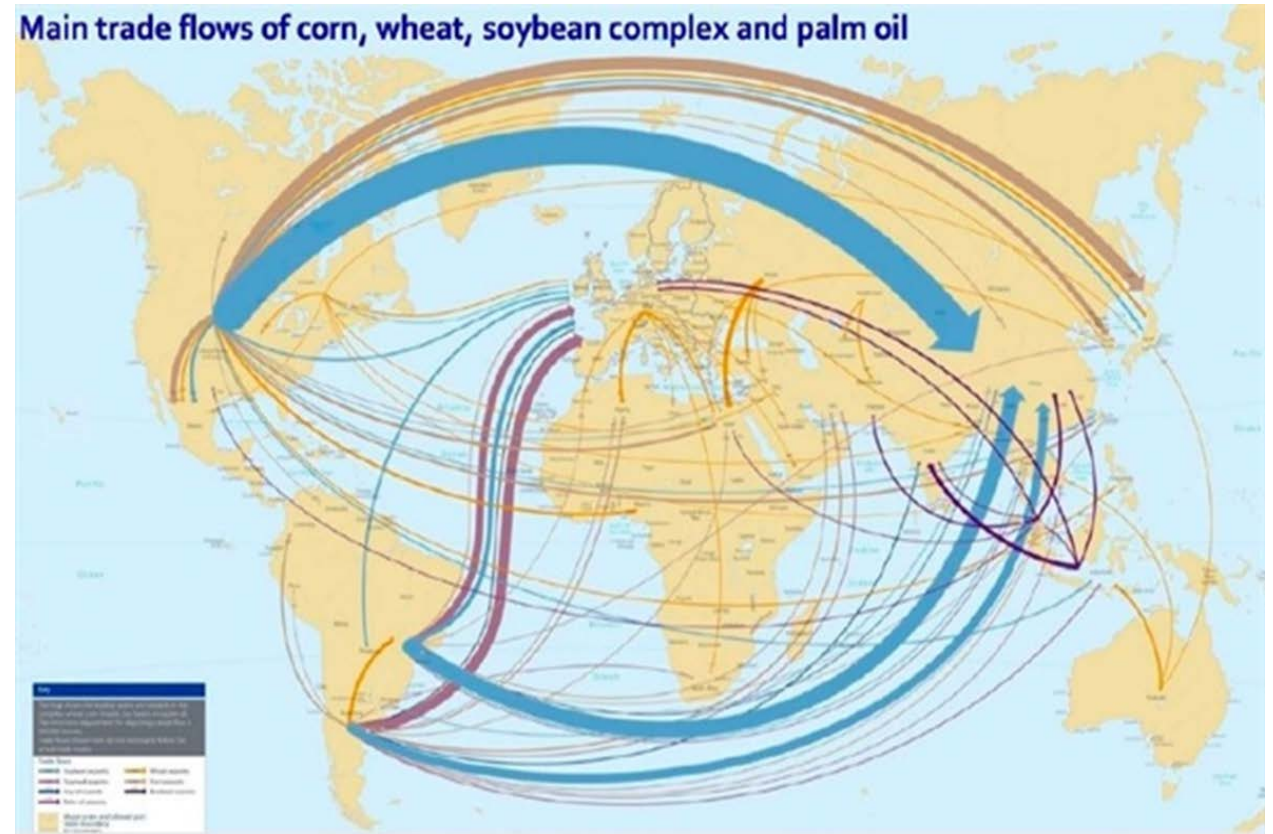**Food Chemicals Codex**

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The supply chain problem

- **One view of the food supply chain is simple, linear, and stable**
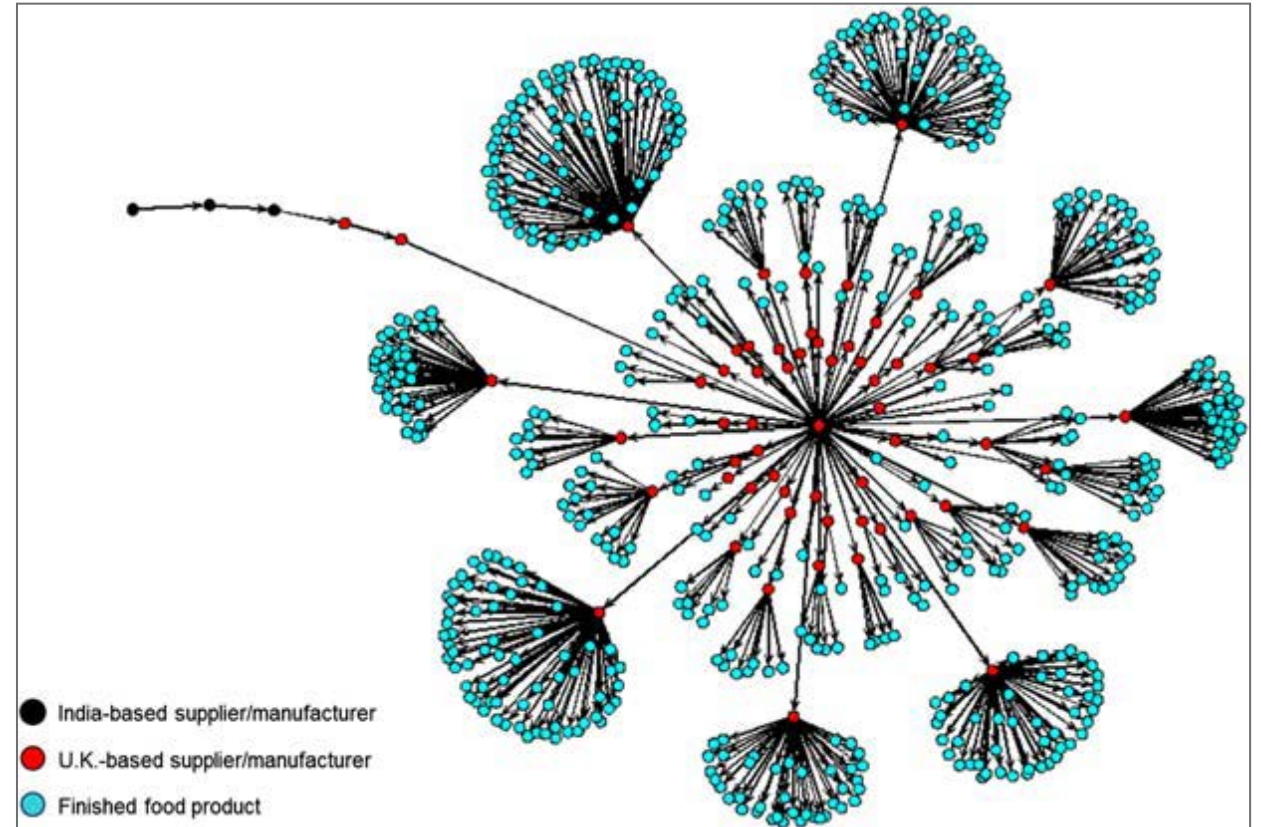
The supply chain problem

- **The reality is that food supply chains are complex, non-linear, and subject to sudden disruption**

- **This creates many opportunities for adulteration, fraud, and misunderstanding**

Main trade flows of corn, wheat, soybean complex and palm oil

Protecting the Supply Chain

- **Learning from our public health colleagues**
  - **Test early and test often**
  - **Supply chain transparency = effective containment**
  - **Communicate accurately and clearly**

Legend:
- India-based supplier/manufacturer
- U.K.-based supplier/manufacturer
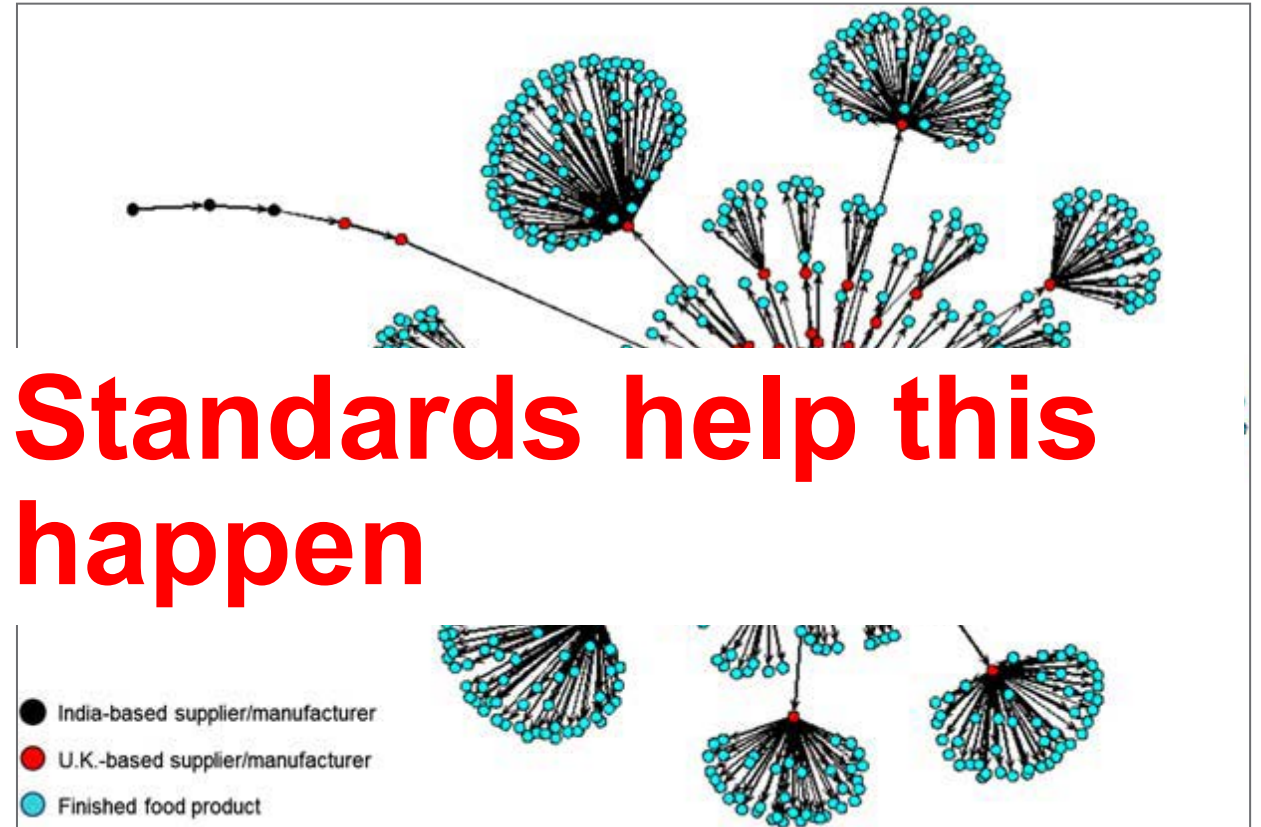- Finished food product

Everstine, K. Supply Chain Complexity and Economically Motivated Adulteration. In: *Food Protection and Security - Preventing and Mitigating Contamination during Food Processing and Production*. Shaun Kennedy (Ed.) Woodhead Publishing: 26th October 2016.

Data source: Food Standards Agency of the U.K. National Archives and The Guardian.

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The Role of Public Standards

Common Language

- Standards help stakeholders speak the same language
- Provide "definition" of quality and purity
- Source of test methods and specifications

Fair Trade

- Ensure the buyers/consumers get what they think they are getting, e.g.:
  - Synthetic vs Natural
  - Purity
  - Source – animal vs. plant

Quality & Integrity

- Ensure Quality & Safety of the food ingredients
- Prevent fraudulent activities
- Standards are based on the ingredient as approved by regulators

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What is a food standard?

- "A set of criteria that a food must meet if it is to be suitable for human consumption, such as source, composition, appearance, freshness, permissible additives, and maximum bacterial content."
  - A Dictionary of Food and Nutrition 2005, Oxford University Press
- Effective standards include both the what and the how
  - What = specifications
  - How = methods

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Standards = Specifications, methods, & materials

- **Specifications are a description**
  - **They set expectations, like highway speed limits**

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  - **It doesn't help to have speed limits on highways if cars don't have speedometers**

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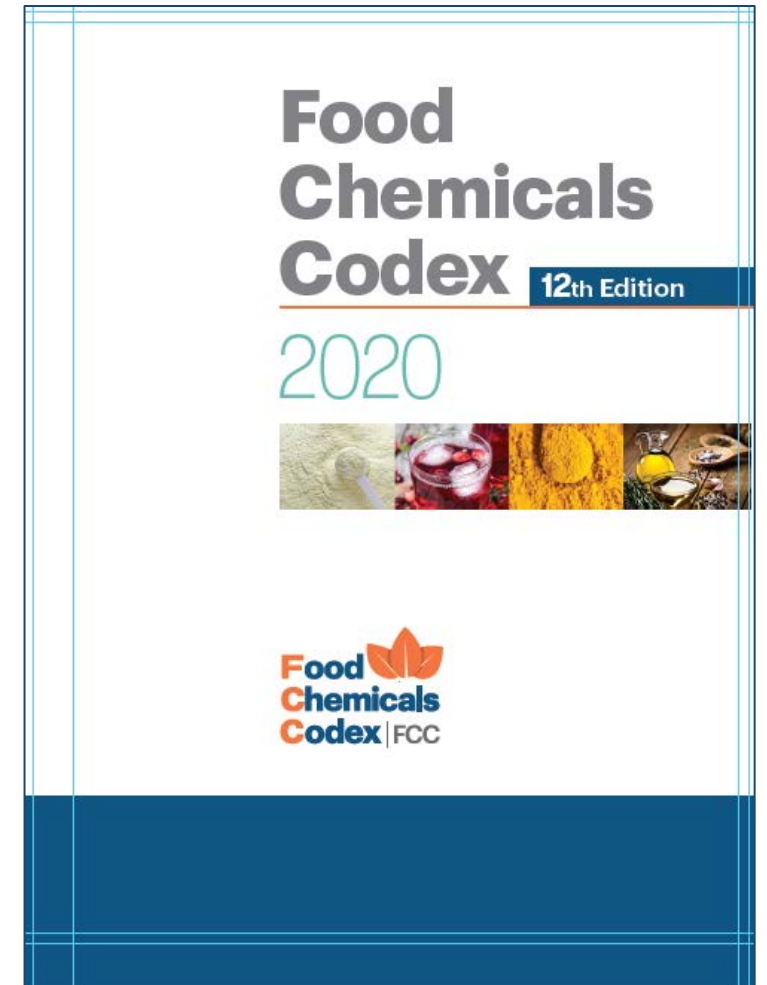# Standards = Specifications, methods, & materials

- **Specifications are a description**
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- **Methods are needed to determine if a sample meets the specifications**
  - **It doesn't help to have speed limits on highways if cars don't have speedometers**

- **Reference materials are used to be sure that the method is working or to evaluate the result**
  - **How do you know that the speedometer in your car or the police radar are accurate (enough)?**

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An Example – The Food Chemicals Codex
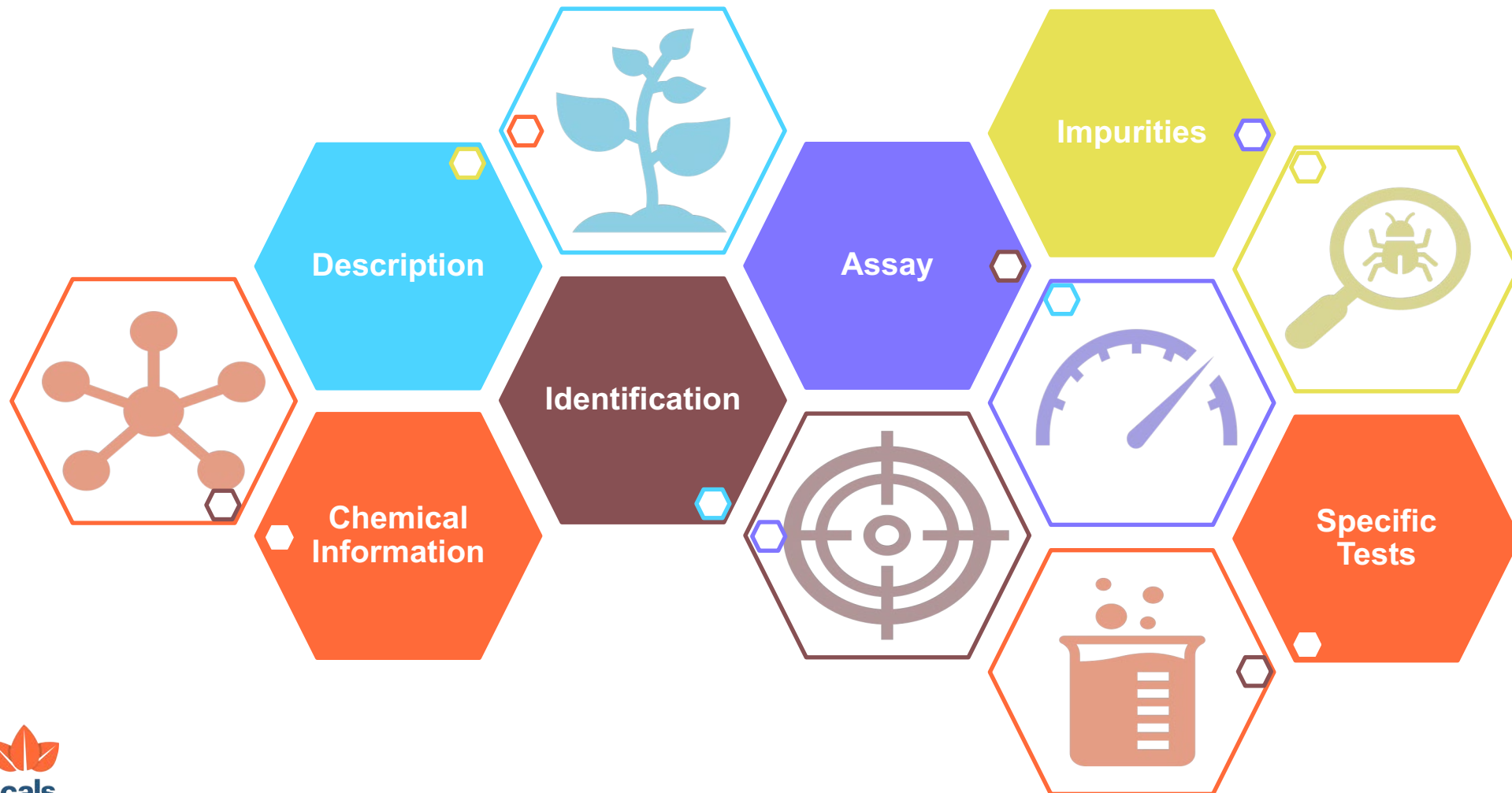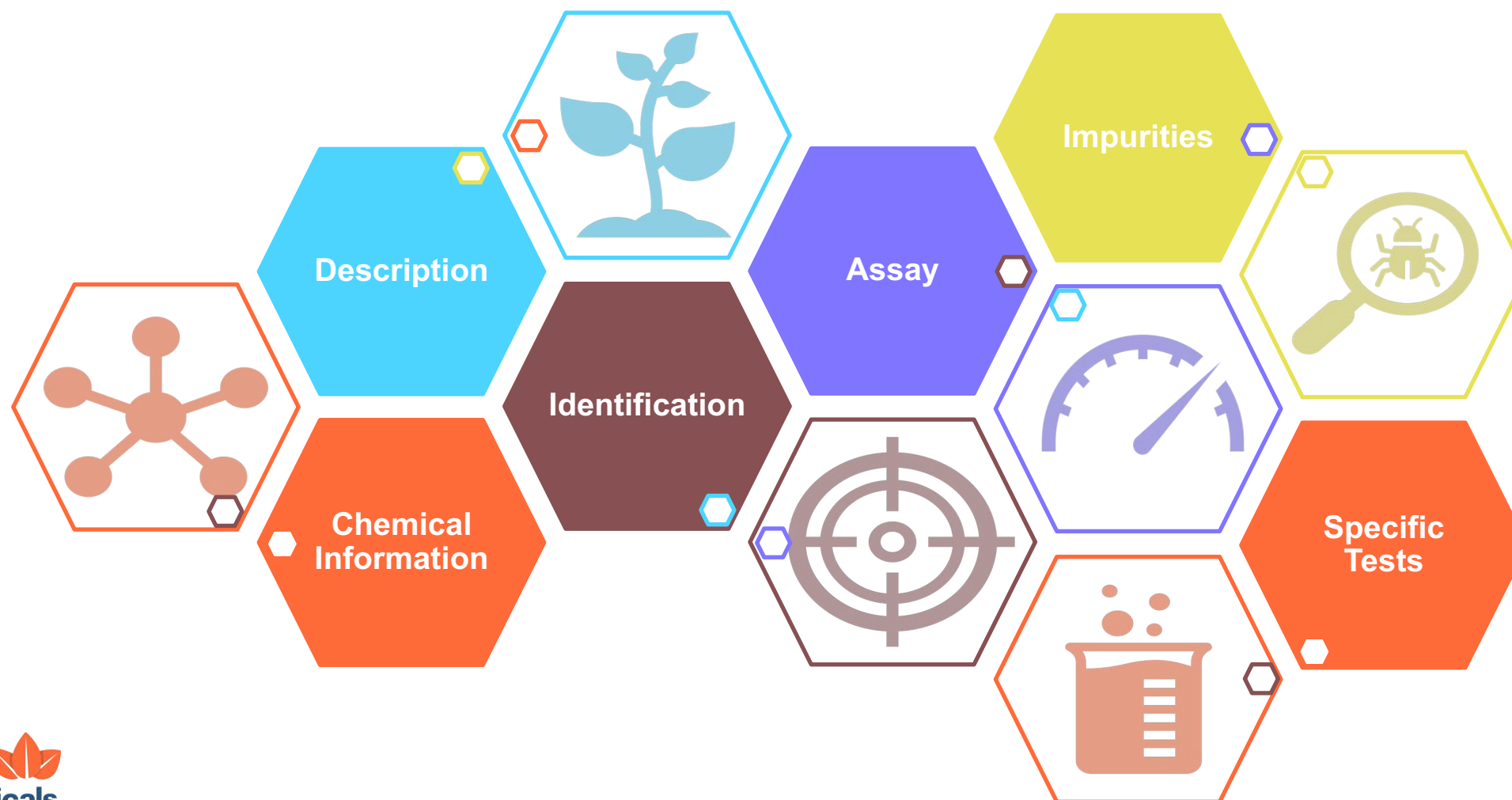
Introduction to the FCC

- **The FCC was created by the US-FDA and the US National Institute of Medicine in 1966**

- **Published by USP since 2006**

- **>1250 standards for additives, ingredients, and other food chemicals**

- **The FCC is the only fully independent source of food ingredient standards**

Food Chemicals Codex 12th Edition 2020

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An Example – The Food Chemicals Codex

SAFEGUARDING THE INTEGRITY OF THE GLOBAL FOOD SUPPLY

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An example of an *FCC* standard – Rice Bran Oil

▲ Rice Bran Oil

Proposed in: Jun 2018

Rice Bran Oil
Oryza sativa Bran Oil
Rice Oil
CAS: [68553-81-1]
UNII: LZO6K1506A

DESCRIPTION

Rice Bran Oil occurs as a clear, yellow, viscous liquid. It is the edible oil obtained by a process that includes pressing, solvent extraction, and refining from the bran of *Oryza sativa*. It is known to contain an antioxidant gamma-oryzanol, a mixture of steryl and other triterpenyl esters of ferulic acids.

Function: Food or salad oil; component of margarine or shortening; coating agent; texturizer

Packaging and Storage: Store in a cool place protected from light in full, tight containers that are made from steel or aluminum and that are suitably lined.

▶ **Descriptive Information**

▶ **Including synonyms**

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An example of an FCC standard – Rice Bran Oil

IDENTIFICATION

- **A. FATTY ACID COMPOSITION, *APPENDIX VII***
  Acceptance criteria: A sample exhibits the following composition profile of fatty acids:

Fatty Acid	Weight % (Range)
12:0	NMT 0.2
14:0	NMT 1.0
16:0	14–23
16:1	NMT 0.5
18:0	0.9–4.0

▸ **Identification tests and purity assays**

▸ **Including acceptance criteria**

ID tests continue

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An example of an FCC standard – Rice Bran Oil

IMPURITIES

Inorganic Impurities

- LEAD, *LEAD LIMIT TEST, ATOMIC ABSORPTION SPECTROPHOTOMETRIC GRAPHITE FURNACE METHOD, METHOD II, APPENDIX IIIB*

   Acceptance criteria: NMT 0.1 mg/kg

- ARSENIC, *ELEMENTAL IMPURITIES BY ICP, APPENDIX IIIC:*   Use nitric acid, rather than aqua regia during the sample preparation.

   Acceptance criteria: NMT 0.1 mg/kg

- WATER, *WATER DETERMINATION, APPENDIX IIB*

   Analysis: In place of 35–40 mL of methanol, use 50 mL of a mixture of chloroform and methanol (50:50, v/v) to dissolve the sample.

   Acceptance criteria: NMT 0.05%

Organic Impurities

- HEXANE-INSOLUBLE MATTER, *APPENDIX VII*

   Acceptance criteria: NMT 0.05%

▸ **Tests and criteria for impurities**

- **B. GAMMA-ORYZANOL IDENTIFICATION**

  Mobile phase: Methanol, acetonitrile, and isopropanol (50:45:5, v/v/v)

  Diluent: Dichloromethane and isopropanol (10:90, v/v)

  Standard solution: 1.5 mg/mL of USP Gamma-oryzanol RS in *Diluent*

  Sample solution: Add 2.5 g of Rice Bran Oil to a 5-mL volumetric flask and dilute with *n*-hexane to volume. Condition the solid phase extraction (SPE) cartridge[1] with two 2-mL aliquots of *n*-hexane. Load 1 mL of the diluted sample onto the cartridge and wash with two 1-mL aliquots of a mixture of *n*-hexane and acetone (99:1, v/v). Elute the cartridge with three 2-mL aliquots of a mixture of *n*-hexane and acetone (91:9, v/v), collect the eluate, and immediately evaporate it to dryness under a stream of nitrogen. Dissolve and wash the residue with 0.8 mL of *Diluent* (200 µL, 4 times), and transfer the solution into a 1-mL volumetric flask. Add *Diluent* to volume.

Chromatographic system, *Appendix IIA*

  Mode: HPLC

  Detector: Diode array detector in the range of 230–400 nm

  Column: 4.6-mm x 250-mm; packed with octadecylsilane chemically bonded to 5-µm porous silica or ceramic microparticles[2]

  Column temperature: 25°

  Flow rate: 1.0 mL/min

  Acquisition time: 60 min

  Injection volume: 20 µL

  System suitability

  Sample: *Standard solution*

▶ **Use of a reference material**

20

What is a reference material

- **ISO Guide 30:**
  - **Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process**
  - **Properties can be quantitative or qualitative, e.g. identity of substances or species.**

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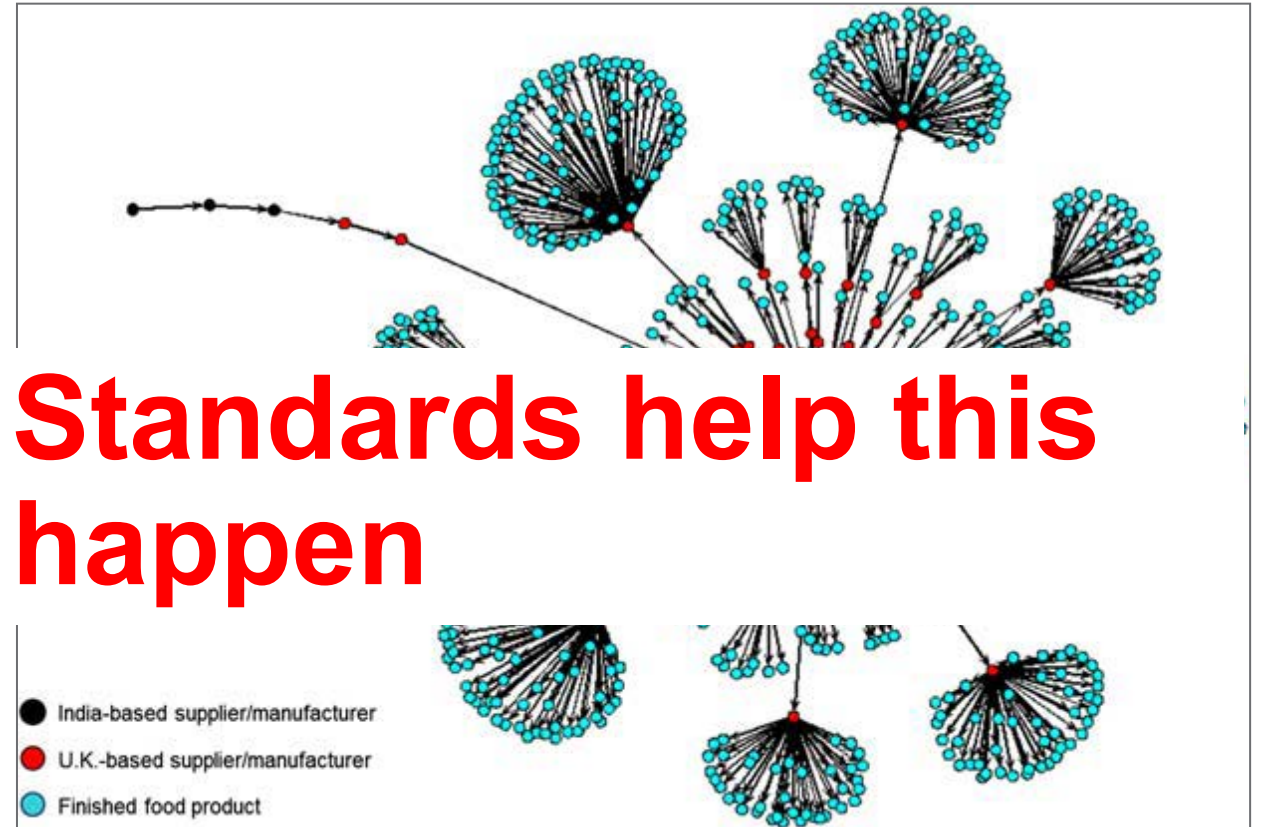
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Uses for reference materials

- **Metrological traceability**

- **Quantitation**

- **System suitability testing**

- **Equipment and procedure calibration**

- **Laboratory controls**

- **Performance testing**

- **Method development and validation**

▸ Based on ISO Guide 33

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Some final thoughts

- **The future is under no obligation to look like the past**
- **We live in a dynamic environment, that can (and does) change rapidly**
- **History is informative, not determinative, when people are the problem (i.e., fraud, EMA, misrepresentation)**

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THANK YOU

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