

Lawsuits and Future Regulations

Purpose

For the past weeks we have looked at food laws and regulations

Talked about government agencies, how they work and what to expect

Focus this week is to talk about external forces

- Public Opinion
- Lawsuits
- Consumer Organizations

“Playing in the Gray”

- Industry name for where there are not clear regulations
- Using the regulations to make the point a company wants to make

I can't tell you where to play or what risks to take

- Companies determine those
- We will look at some of the risk and try to give you some idea of where to look and what information is helpful in making the decisions

Everyone's opinion counts

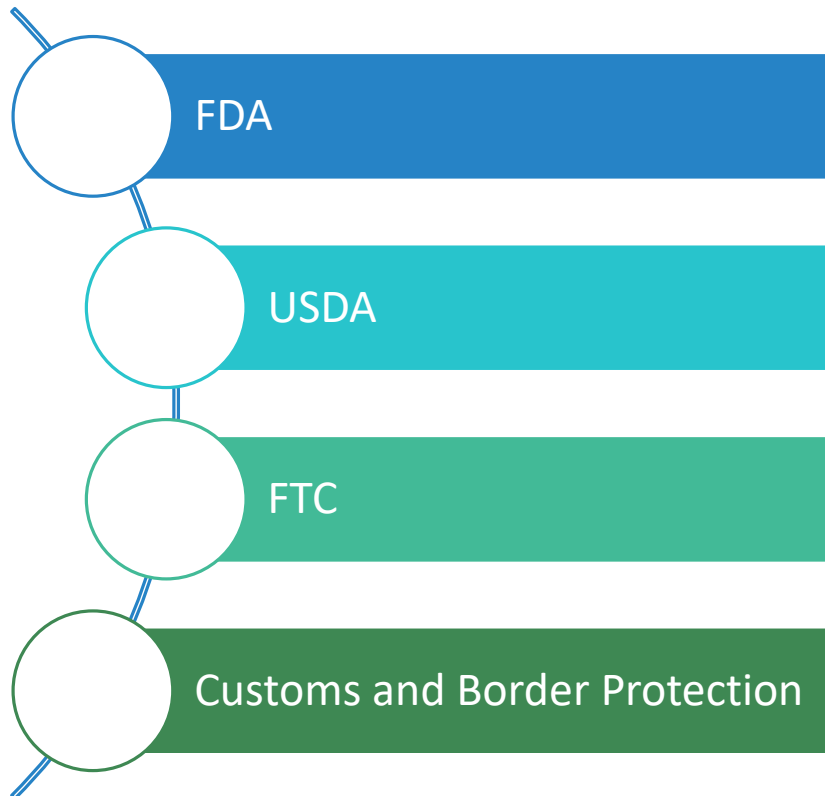
WE ARE LOOKING AT THE HOW TO GET THERE NOT
THE FINAL DECISIONS

Risk Assessment



US Regulatory System

REGULATORY AGENCIES



INTERESTED PARTIES



Consumer Groups

Organizations who support consumer interest

Not as influential in the US as in the EU

Financial support from consumers

Actions

- Petition FDA for new regulations
- Letter to consumers regarding issues
- Lawsuits against industry
 - Most lawsuits are settled if industry agrees to make some changes

Meet with limited success getting changes

BBB CFBAI

Better Business Bureaus Children's Food and Beverage Advertising Initiative

Set up because of increases in child obesity

Set voluntary standards to control what foods are advertised to children

Companies sign up for group voluntarily

Critics claim this does not go far enough

Trade Groups

Supported and paid for by food industry

Support industry in policy issues

One way for the entire food industry to work together

Usually avoid competitive issues

Relatively influential in the US

Health Organizations

Usually made up of health professionals

Support improved health

Avoid political issues

Try to keep positions based in science

Legal Actions

Used to bring about changes to food industry

Ensure food safety

Bring changes to foods that are in gray of food regulations

Brought by

- Private Citizens
- Consumer Groups
- Other Food Companies
- Government Agencies

Health claims on cereal

High Fructose Corn Syrup on natural

GMO on natural

Lawsuit Outcome

Food companies settle lawsuits for a lot of reasons

- Guilt
- Save money
- To make this go away
- They determine it is not worth the publicity

Some of these companies are worth a lot of money and settling is the cheapest option

- “The first hit is always the best hit”

Lawsuits sometimes bring regulatory changes

Recent Food Lawsuits

Evaporated Cane Juice

In 2009 FDA issued labeling guidance

Juice is defined as the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

- 21 CFR 120.1(a)

Should be labeled as sugar or syrup

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm181491.htm>

FDA Notice

March 2014 FDA reopened comment period on ECJ

May 214 comments were due

No additional information from FDA

Evaporated Cane Juice Lawsuits

Chobani

- Argued that consumers know cane is a sweetener
- Won the suit and is able to continue to label ECJ

Amazon Preservation Partners

Healthy Beverage LLC

Santa Cruz Natural, INC

Late July Snacks

Blue Diamond

Trader Joe's

Wallaby Yogurt Co

Evaporated Cane Juice Lawsuits cont...

White Wave

- Settled
- Remove ECJ from label

Whole Foods

- Still in process
- Claims consumers know ECJ is sugar

Natural

Limited regulations

States must be from plant or animal

- 21CFR101.22

Color is not allowed

- FDA compliance guide

USDA adds minimally processed

- Standard and Labeling Policy Book

Not a clear definition

Has lead to lawsuits

- Some for artificial ingredients
- Some for ingredients that meet 21CFR101.22
 - Examples – High Fructose Corn Syrup, GMO

Whole Foods Natural

Sodium Acid Pyrophosphate (SAPP)

- Chemical used as leavening and preservation

Suits in California and Arkansas

FDA warning letter

- Alexia (ConAgra Foods)
- SAPP is not natural
- Agreed to remove natural from label

Other suits against Whole Foods

- Ginger Ale and Root Beer
 - Carmel color, citric acid, carbon dioxide

Court and FDA

In 3 cases judges ask FDA to define natural

- Gruma Corp
- Campbells
- General Mills

FDA sent letter back to courts declining to respond

Must go through rule making process

FDA has issued a proposed rule

- More information in assignment

Natural Lawsuits

Kellogg's Kashi

- GMO
- Settled \$5 million

Stevia in the Raw

- Maltodextrin and dextrose from GMO
- Carriers for the product
- Settled for \$1.5 million

B&G Foods

- Bagels chips
- GMO
- Highly processed
- In process

Natural Lawsuits cont...

PopChips

- GMO and highly processed
- Settled for \$2.4 million

Trader Joe's

- Ascorbic acid, cocoa processed with alkali, xanthan gum, mono- and diglycerides, SAPP
- Settled

Pepsico

- Naked Juice with GMO
- Settled for \$9 million

Natural Lawsuits cont...

General Mills

- Nature Valley
- High fructose corn syrup, maltodextrin
- Sued by CSPI
 - CSPI is not typically after money
- Removed claim

Kraft

- Cheese
 - Citric acid and natural flavors
 - Still in process

Capri Sun

- GMO
- Still in process

ConAgra

- Wesson Oil
- GMO
- Still in process

Spray Butter

Lawsuits over 0 calorie and fat free claim

- Claim on serving size
- Bottle contains approximately 832 calories and 93 g of fat

Consumers were eating large quantities

- Serving size 5 sprays

Suits vs

- ConAgra Parkay
- Unilever I Can't Believe It's Not Butter

No settlements listed



Cheerios Protein

CSPI sued General Mills

States Cheerios Protein has smidgen more protein and 17 times the sugar

11 total grams of protein

- 4 g of protein is coming from milk

Larger serving size than “original” Cheerios

- 28 g vs 55 g

No decision yet



High Fructose Corn Syrup

CSPI has sued Kraft and General Mills

- HFCS is not natural

Companies have been removing this

Corn Refiners Association submitted petition to change name of HFCS

- Name corn syrup
- FDA denied petition

Many companies removing HFCS from products

Many nutritionist claim metabolized like all other sugars



Chobani Ingredient Advertising

Chobani created advertisement talking about ingredients

Ingredient include

- Potassium Sorbate
- Sucralose
- FDA regulations as ingredients are same

January 2016 Dannon and General Mills (Yoplait) sued for defamation

Outcome TBD

Will FDA or FTC respond?



Criminal Labeling Issues

Convicted of changing labels

Economic adulteration

- Misbranding in 9CFR

Islamic Services of America owner William Aossey, Jr

Changed EST on meat labels

- To make product appear Halal approved

Exported products as Halal at higher prices

Early criminal case for labeling issues

Seeing more food safety issues where criminal charges are prosecuted

- Would expect labeling issues to increase as well



Company Policies

Whole Foods GMO Policy

GMO required to be removed from products sold in their stores

Currently focused on private label products

What removed from all brand name products

2018 is goal

No clear definition of GMO

- EU has definition
- Non GMO project has definition



Whole Food Ingredient Policy

Has a list of ingredients not to be used in their stores

Connect it to natural foods

- No real connection
- This company's opinion

Companies follow this requirement or don't sell in Whole Foods



Panara Bread Ingredient Policy

Established a list of ingredients that are allowed in products they serve

- Refer to as clean ingredients

Prohibited

- Artificial flavors
- MSG
- Artificial trans fat
- Artificial colors
- Artificial sweeteners
- Preservatives



Sustainability

What companies are doing to help the environment

Programs vary by company

No regulations around

Some examples of topics

- Ingredients
- Recycling
- Reducing water use
- Reducing electricity
- Packaging
- Transportation
- Waste management



Fair Trade

Social movement to ensure everyone is able to make a living wage

Typically for ingredients and products that are imported from 3rd world countries

Examples

- Coffee
- Tea
- Cocoa



Dietary Guidelines

Advised USDA and FDA on nutrition policy

Gives a final report of nutrition status in the US

Developed every 5 years

Written by a committee of experts

- Appointed by FDA/USDA
- Nominated through a Federal Register notice

Alternate between FDA and USDA

- Completed and joint activity



What is Next???

POTENTIAL NEW REGULATIONS

INDUSTRY DISCUSSIONS

OTHER HAPPENINGS

USDA

Seems to be focusing on food safety regulations

Finalized performance standards for NRTE poultry

- February, 2016

Project on retail food safety

- Collecting data
- Pending results regulations could come

Still working on risk based inspection

- Some poultry regulations
- Expect more

FDA nutrition labeling regs could lead to nutrition labeling changes

FDA

Is working on a wide variety of new regulations

Finalized

- Nutrition labeling
- Menu labeling (previously discussed)
- Vending machine labeling (previously discussed)

ANPR

- Natural
- Gluten Free

Coming next

- A few ideas are included below
- It is unknown what will happen next

Nutrition Labeling

Expected in March 2016

Compliance 2 years from date of publication

First major change since 1995

Will increase size of calories

Make servings per container more visible

Add added sugar

Potentially change fiber definition

Change vitamins and minerals

- Potassium and Vitamin D in
- Vitamin A and C out

Nutrition Labeling Proposed Panel

CURRENT

Nutrition Facts			
Serving Size 2/3 cup (55g)			
Servings Per Container About 8			
Amount Per Serving			
Calories 230	Calories from Fat 40		
% Daily Value*			
Total Fat 8g	12%		
Saturated Fat 1g	5%		
Trans Fat 0g			
Cholesterol 0mg	0%		
Sodium 160mg	7%		
Total Carbohydrate 37g	12%		
Dietary Fiber 4g	16%		
Sugars 1g			
Protein 3g			
Vitamin A 10%			
Vitamin C 8%			
Calcium 20%			
Iron 45%			
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

PROPOSED

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per 2/3 cup	
Calories	230
% DV*	
12%	Total Fat 8g
5%	Saturated Fat 1g
	Trans Fat 0g
0%	Cholesterol 0mg
7%	Sodium 160mg
12%	Total Carbs 37g
14%	Dietary Fiber 4g
	Sugars 1g
	Added Sugars 0g
	Protein 3g
10%	Vitamin D 2mcg
20%	Calcium 260mg
45%	Iron 8mg
5%	Potassium 235mg
* Footnote on Daily Values (DV) and calories reference to be inserted here.	

Salt and GRAS

CSPI has called for removal of GRAS status for salt

FDA has had petition for a few years

Most likely will not act

Salt is required for food safety in some cases

New calls are for sodium reduction requirements

- Industry has done voluntary sodium reduction
- Several groups have provided industry guidance

Outcome unknown

- Regulations unlikely
- Guidance on sodium levels possible



Natural

FDA ANPR on natural

Comments due May 2016

Unclear what FDA will decide

Industry does not have consistent views

Could be years before final rule



Gluten Free

Gluten free finalized in 2013

Allowed voluntary labeling

10 ppm standard

Fermented and hydrolyzed gluten products

- Proposed rule November 2015
- FDA looking for data to support allowing
- Some limited data was available
- FDA has not responded
- Predict it will be a while until science evolves



FDA Food Safety

FMSA

- Food Safety Modernization Act

Requires

- Preventive controls
 - Risk analysis
 - Controls for risks
- Supplier controls
 - Know where ingredients are coming from
 - Supplier approval programs
- Import controls
 - Supplier controls
 - Inspections
- RAC
 - Raw agricultural commodities
 - Special controls and process for fruits and vegetables
- Mandatory Recall

Transportation still to be finalized

Most early 2017 compliance

Cooking Instruction Validation

USDA passed first regulation requiring cooking instruction validation in 2015

Currently most NRTE USDA foods have validated cooking instructions

- Developed after recalls
- Banquet pot pie
- Totino's pepperoni pizza

If additional recalls look for USDA to expand recalls

FDA may follow in a number of years



Food Colors

FSA (Food Safety Authority) in UK published a study stating that research indicated there was a link between hyperactivity in children and artificial (FD&C) colors

2008 UK ask companies to remove FD&C colors from food

2009 EU ask companies to remove FD&C colors from food

2012 – 2015 US food companies began voluntarily removing FD&C colors from foods

- General Mills cereal
- Kraft Mac and Cheese



Siluriformes Fish

Catfish family

2008 Farm Bill made this product USDA amenable

- Passed by Congress

MOA between USDA and FDA

- Help to make the transition smooth
- Outline responsibility of each agency

18 month transition period to get compliant

Sample of new USDA bug for fish products



Single Food Agency

Most countries around the world have all food regulated by 1 food agency

US has 2 food agencies

- USDA
- FDA

Comes up about every 10 years

- Seeing some rumblings

Food industry unsure of position

Would it be more efficient to just have 1 agency

Would it save money for the government

Would it make food safer

Food vs Dietary Supplement

Line between food and dietary supplement is not clear

Very different rules for claims

Companies have been able to choose if product was a food or dietary supplement in past

FDA provided guidance on beverages vs dietary supplement

- Serving size seems to be the determination

Monster beverages changed from dietary supplement to food



FDA GRAS

Was very hot in 2014 and early 2015

Has been quieter recently

FDA was discussing if GRAS process should be changed

Are unsafe ingredients getting into the market

Big companies appear to be doing due diligence

Unsure when and if changes will occur

- FDA moves slowly on issues like this

Writing Federal Register Comments

Must include docket number

Start with a thank you paragraph to government agency

List comments clearly and concisely

Use sub-headings to make comments clear

1 comment per paragraph

- If making multiple comments on same issue 1 paragraph for each

End with a thank you for being allowed to comment

Writing Federal Register Comments cont...

Your assignment to write comments

Pick 3 or 4 items you want to address

Provide support for your agreement

- Show data or links to support
- Is acceptable to use industry examples to support comments

May use opinions

- However unlikely to sway the FDA or USDA
- Facts or examples are better for influencing the position

Be clear and concise

Assignment comments should be 2 to 4 pages