

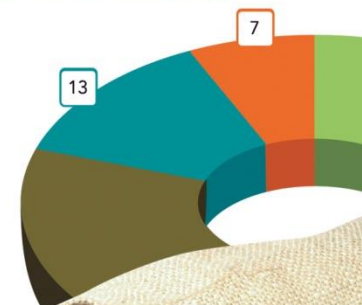


# National Coffee Association

## Coffee Science: What You Don't Know COULD Hurt You – Current Science & Regulatory Issues

March 18, 2016

nca  
NATIONAL COFFEE ASSOCIATION USA EST. 1911



# NCA Scientific Advisory Group

- ☐ National Coffee Association (NCA) – Scientific Advisory Group (SAG)
  - ☐ Separately funded work group of the NCA
  - ☐ Commissioned in 1967
- ☐ Contributor companies include:
  - ☐ Starbucks Co.
  - ☐ J.M. Smucker Co.
  - ☐ Keurig Green Mountain, Inc.
  - ☐ America's Food Technologies, Inc.
  - ☐ Kraft Foods, Inc.
  - ☐ Coca Cola Co.
  - ☐ Nestlè USA
- ☐ Joined by:
  - ☐ Specialty Coffee Association of America (SCAA)
  - ☐ Coffee Association of Canada
  - ☐ Institute for Scientific Information on Coffee (ISIC)
  - ☐ European Coffee Federation (ECF)
  - ☐ Top-Notch industry consultants (M.D., epidemiologist, toxicologist)

# Presentation Overview

- ☐ Caffeine
- ☐ Diacetyl & Flavor Safety within a context of Occupational Exposure and Industrial Hygiene
- ☐ Food Safety Modernization Act (FSMA)
- ☐ International Agency for Research on Cancer (IARC) review of coffee in 2016
- ☐ Coffee & Health

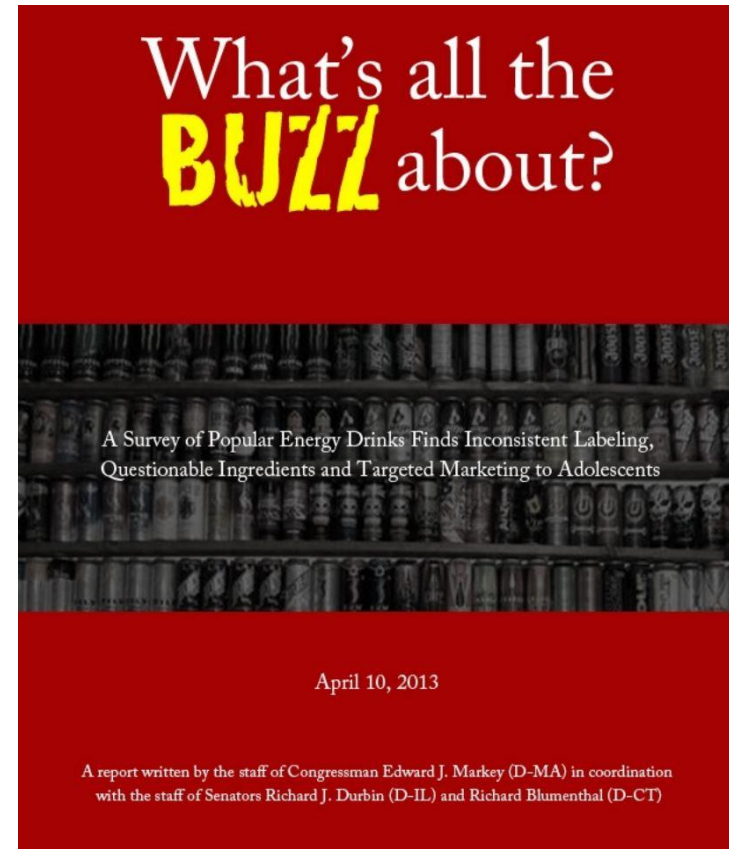
# Caffeine





# Congress & FDA Concerns over Caffeine: US Senate Report Released April, 2013

- ❑ Report by Offices of (then) Rep. Markey (D-MA), Sen. Durbin (D-IL) and Sen. Blumenthal (D-CT), April 10, 2013. Their main arguments were:
  - ❑ Inconsistent representation and claims
  - ❑ Inadequate labeling
  - ❑ Unsubstantiated claims of benefits
  - ❑ Targeting children
  - ❑ Effects of other constituents unknown



# HOW MUCH CAFFEINE? IS IN YOUR BEVERAGE?

40-70 mg



SOFT DRINK  
(with caffeine)

160-240 mg



ENERGY DRINK

300-330 mg



COFFEEHOUSE COFFEE



Most energy drinks contain significantly less caffeine than a similarly-sized coffeehouse coffee. In fact, many only contain about half.

AMERIBEV.ORG

BASED ON 16 OUNCES

Information was obtained from the Center for Science in the Public Interest, the Mayo Clinic, energyfiend.com & the FDA

# NCA Website - Caffeine

<http://www.ncausa.org/Health-Caffeine>

## How Much Caffeine Is In Your Coffee?

Brewed coffee

8 oz

Average: 95 mg

Range: 75 - 165



Brewed decaf

8 oz

Average: 2 mg

Source: Mitchell, et al - 2014

# Concern over added caffeine in foods & beverages



Safety concerns have been raised over energy drinks and food and beverage products containing added caffeine.



# Caffeine

- ❑ 96% of beverage caffeine is consumed from coffee, tea, and soft drinks. Coffee is the largest contributor.
- ❑ Energy drinks, energy shots, and chocolate beverages contribute little to caffeine intake
- ❑ Teenagers (13-17 years) or young adults (18-24 years) – 9-10% of their caffeine intake comes from energy drinks.
- ❑ Intakes from energy drinks represent less than 2% of total daily mean caffeine values for all caffeinated beverage consumers.

Source: International Life Sciences Institute

# Caffeine

- ❑ International Life Sciences Institute (ILSI) North America is conducting a systematic review on caffeine safety
- ❑ Systematic review is gold standard for reviewing literature
- ❑ 700+ articles reviewed
- ❑ Will be most complete review conducted since Nawrot et al (2003)
  - ❑ Authors cited 400 mg as a reference value for no adverse effects
  - ❑ ILSI NA systematic review will evaluate Nawrot et al (2003) work and any new published studies.
- ❑ The NCA SAG provided an unrestricted grant to help fund the review
- ❑ There has been open dialogue with the FDA on the work completed thus far and what is planned.

# Diacetyl & Flavor Safety – Occupational Exposure

# Diacetyl

- ☐ Classified as a Flavor
- ☐ Clear yellow to yellowish green liquid with strong pungent odor; typical buttery odor and flavor
- ☐ Common constituent of flavor formulations
  - ☐ Examples: Strawberry, Caramel, Hazelnut and Butterscotch
- ☐ Utilized in the food and beverage industries as a synthetic flavor and aroma carrier
  - ☐ Butter
  - ☐ Vinegar
  - ☐ Dairy Products
  - ☐ Coffee
- ☐ Naturally found in foods
  - ☐ Butter, cheese, milk, yogurt
  - ☐ Processed tomatoes, citrus fruits, guava, juices
  - ☐ Black tea, coffee, beer, wine, whiskey, cognac



# Diacetyl

- ❑ Regulatory Status
- ❑ Diacetyl, also known as 2,3-Butanedione
- ❑  $C_4H_6O_2$ ; CAS Reg. No. 431-03-8
- ❑ Generally Recognized As Safe (GRAS) 21 CFR § 184.1278
- ❑ Direct Food Substances Affirmed As Generally Recognized as Safe
  - (1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.
  - (2) The ingredient is used in food at levels not to exceed current good manufacturing practice
- ❑ Food Chemical Codex Specification published in 1981

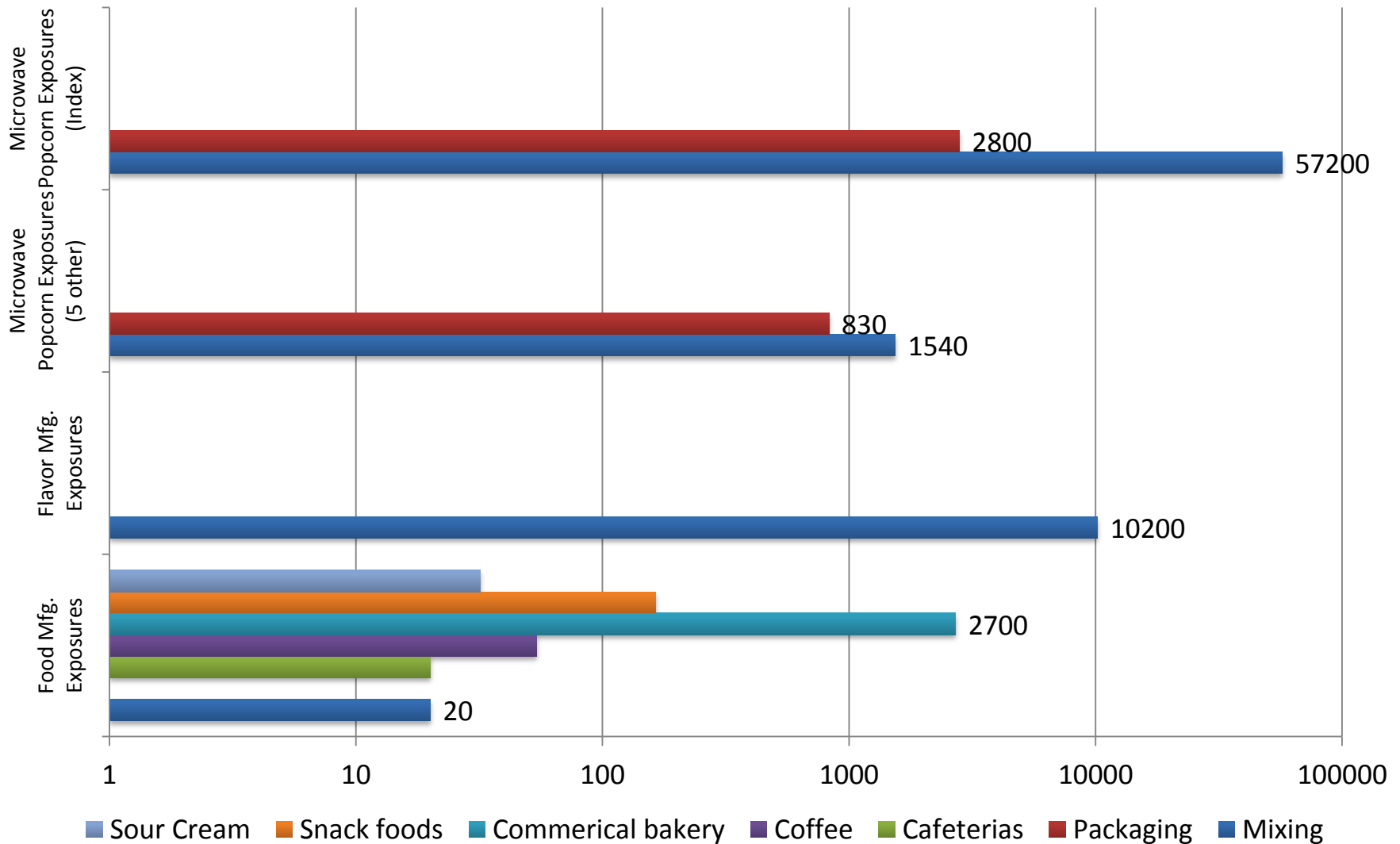
# Diacetyl & Flavor Safety

## Brief history of key events:

- ❑ Gilster Mary Lee – popcorn
  - ❑ Epidemiology cluster
  - ❑ Begins association with respiratory issues from workplace
  - ❑ Specifically Bronchiolitis obliterans (BO) gains attention
- ❑ Many surprised to learn...there were earlier cases
  - ❑ Cases in baking industry going back to the 1980's
- ❑ Political demand for action ahead of the science
- ❑ Emphasis remained on popcorn manufacturing & flavor houses
  - ❑ FEMA guidance comes out (2002)
- ❑ Food industry including NCA becomes more involved (2006)
- ❑ Pressure from Congress/OSHA rulemaking proposed/Cal OSHA/NIOSH work

***It's very important to note diacetyl is a "marker" compound and hasn't been identified as the sole chemical of concern.***

# Exposures – Perspective to Suggested OEL's



# Diacetyl & Flavor Safety

## Past 3 years

- ☐ NIOSH Peer review by expert panel – not very transparent
- ☐ No real evidence of response to public comments
- ☐ Rumors of REL finalizing
- ☐ No evidence of “epidemic” that was predicted
- ☐ Industries continue to get fined/cited/sued

## Past year

- ☐ Some recent publications highlight coffee levels could be high
- ☐ Texas lawsuit related to coffee
- ☐ Media attention increases
- ☐ OSHA likely to move slowly to rule-making
- ☐ Consumer questions/member questions/worker questions



# Diacetyl & Flavor Safety

- ❑ NCA submitted 2 rounds of comments –Challenged scientific rigor used by NIOSH
- ❑ Highlights
  - ❑ **Historically – not an abundance of cases** and most have been observed in flavor manufacturing & microwave popcorn despite potential for exposure in other industries.
  - ❑ **Exposure is likely very different** (e.g., there are cases of very sick people from high level exposure)
    - ❑ The focus has always been on Gilster Mary Lee where there is a **lot of uncertainty in exposure**; If NIOSH underestimated exposure, then everything is skewed extremely conservatively
    - ❑ NIOSH had Health Hazard Evaluations (HHE) reports on other food industries **but focused on high dose only**
    - ❑ **Misperceptions Perpetuated**- Because of the way the data is presented, one may assume an 8 hour exposure could lead to much higher exposures than what the data actually demonstrate

# Diacetyl & Flavor Safety – Potential Business Impact

- ❑ Multiple lawsuits
- ❑ Historically centered around popcorn industry and flavor manufacturers
  - ❑ 2001 popcorn workers filed lawsuit
- ❑ 2012 Consumer filed lawsuit against microwave popcorn manufacturer
  - ❑ Awarded \$5 million in damages

❑ **Is this the start of a new trend?**

- ❑ **2012 Texas Coffee workers filed lawsuit**

# Perspective is CRITICAL

- ❑ In the popcorn industry, exposure to flavor was extremely high (nearly neat diacetyl, bending over heated open vats, repeated exposure)
- ❑ Each manufacturing site may be different
  - ❑ One size does not fit all
- ❑ Are workers seasonally exposed? Are they even exposed?
  - ❑ Taking measurements should be done with the proper method with an industrial hygienist involved and with the appropriate benchmark in mind.
  - ❑ In Industrial Hygiene, one does not monitor if you don't know what to do with the data (e.g., what to compare it to as the safe level)
- ❑ It's important to remember safety concerns are not solely diacetyl (2,3-pentanedione, acetoin, acetaldehyde, acetic acid, furfural have also been identified as potentially concerning to OSHA)
  - ❑ Diacetyl continues to be the “marker” compound used in discussion.

# Diacetyl & Flavor Safety

- ❑ Members of the NCA have received questions from workers, the media, and auditors on diacetyl & flavor safety for Occupational Exposure
- ❑ Realizing that the 5 ppb REL set by NIOSH is very low, there is heightened interest in determining what is a realistic number for the coffee industry
- ❑ Working in a coordinated manner, the NCA SAG has:
  - ❑ Created a working group within SAG (Sep 2015)
  - ❑ Solicited proposals from multiple toxicology consultancies specializing in diacetyl & flavor safety (Dec 2015)
  - ❑ Currently gaining internal alignments and securing funding to initiate work (Present)
  - ❑ Set goals:
    - ❑ Immediate goals: To conduct a literature review and determine OEL for diacetyl & 2,3-Pentandione
    - ❑ Long-term goals: Determine how to engage NIOSH/OSHA, possibly develop an Industry Code of Practice and other steps



FSMA

# FSMA

- ❑ FDA Food Safety Modernization Act (FSMA) – Signed into law on Jan. 4, 2011
- ❑ Aim is to instill **preventive controls** for food safety:
  - ❑ **Prevention** – Implement written preventive controls plan
  - ❑ **Inspection and compliance** – Inspection frequency, records access, lab accreditation
  - ❑ **Response** – FDA will have authority to issue a mandatory recall
  - ❑ **Imports** – Programs to ensure imported foods meet U.S. food safety standards
  - ❑ **Enhanced partnerships** – FDA will create or strengthen strategic and integrated collaborations with government associations at federal, state, and local levels, and foreign governments
- ❑ <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm>

# FSMA Rule Timelines

Proposed Rule	Final Rule Published	Implementation Requirements	Deadline
Preventive Controls for Human Food	September 17, 2015	~1 year after final rule	September 19, 2016
Preventive Controls for Animal Food	August 30, 2015	~1 year after final rule	August 30, 2016
Produce Safety	October 31, 2015	2 years + 60 days after final rule	December 31, 2017
Foreign Supplier Verification Program	October 31, 2015	18 months from final rule	April 31, 2017
3 <sup>rd</sup> Party Accreditation and Certification	October 31, 2015	After Model Accreditation Standards	--unknown--
Sanitary Transportation	March 31, 2016	1 year after final rule	March 31, 2017
Food Defense	May 31, 2016	1 year + 60 days after final rule	July 31, 2017

# Compliance Dates for Human Rule

Staggered by business size

- ☐ Most– September 19, 2016
- ☐ Small Businesses – September 18, 2017
- ☐ Very Small Businesses – September 17, 2018
  - Paperwork documenting it is a “very small business” must be filed by September 2016

Supply chain program compliance

- ☐ 6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the applicable rule.



# FSMA Human Rule Key Requirements

- ❑ Good Manufacturing Practices – cGMP
  - ❑ “shall” language changed to “must”
  - ❑ New 21 CFR §117 Subpart B replaces 21 CFR §110
- ❑ Food Safety Plan
  - ❑ Must be written
  - ❑ Must be overseen by Preventive Controls Qualified Individual (PCQI)
- ❑ Supply Chain Program
- ❑ Recordkeeping

# GMP Key Sections

- ☐ Personnel
- ☐ Plant and grounds
- ☐ Sanitary operations
- ☐ Sanitary facilities and controls
- ☐ Equipment and utensils
- ☐ Processes and controls
- ☐ Warehousing and distribution
- ☐ Defect action levels

# Food Safety Plan Components

All sections must be written and available for review

- ☐ Hazard analysis
- ☐ Preventive controls (PC)
  - GMPs may be preventive controls
- ☐ Supply chain program
- ☐ Recall plan
- ☐ Implementation and monitoring of PC
- ☐ Corrective action procedures
- ☐ Verification procedures

# Supply Chain Program

## Required elements

- ☐ Use of approved suppliers
  - ☐ Determine appropriate supplier verification activities (including audit frequency)
  - ☐ Conduct supplier verification activities
  - ☐ Documenting supplier verification activities
  - ☐ Verify supply-chain applied control by entity other than receiving facility (if applicable)
- 
- ☐ Examples of supplier verification activities
    - ☐ Onsite audits; sampling and testing; review of supplier food safety records

# Records

## Required records

- ☐ Documentation of basis for not establishing preventive control (if applicable)
- ☐ Documentation of corrective actions
- ☐ Validation documentation
- ☐ Verification of monitoring and corrective action effectiveness
- ☐ Calibration documentation
- ☐ Product testing results
- ☐ Environmental testing
- ☐ Records review
- ☐ Reanalysis of food safety plan
- ☐ Supply chain verification documentation
- ☐ Training records



# Qualified Individual vs. Preventive Control

## Qualified Individual

- ❑ **Qualified individual (QI)** means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.
- ❑ **Preventive controls qualified individual (PCQI)** means a qualified individual who has successfully *completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA* or is otherwise qualified through job experience to develop and apply a food safety system.

# International Agency for Research on Cancer – Review of Coffee in 2016

# IARC Review of Coffee

## Background:

- ❑ International Agency for Research on Cancer (IARC) is the specialized cancer agency of the World Health Organization (WHO)
- ❑ IARC develops Monographs that represent the consensus of a working group of expert scientists
- ❑ Evaluation is a hazard identification, not a risk assessment
- ❑ In 1991, IARC reviewed coffee and cancer safety. They classified coffee as 2B – Possibly carcinogenic to humans.
- ❑ Coffee is scheduled for review in May, 2016.
- ❑ In 2015, IARC released a report on processed meats as Class 1 carcinogens and fresh red meat as Class 2A carcinogens.

# Monograph – IARC Classification

IARC classifications:

<b>Group 1 (carcinogenic to humans)</b>	Sufficient evidence in humans or sufficient evidence in animals and strong mechanistic data in humans
<b>Group 2A (probably carcinogenic to humans)</b>	Limited evidence in humans and sufficient evidence in animals
<b>Group 2B (possibly carcinogenic to humans)</b>	Limited evidence in humans and less than sufficient evidence in animals
<b>Group 3 (unclassifiable as to carcinogenicity in humans)</b>	Inadequate in humans and inadequate or limited in animals
<b>Group 4 (probably not carcinogenic to humans)</b>	Lack of carcinogenicity in humans and in animals

*Coffee last evaluated in Monograph 51 (1991)  
is currently IARC 2B*

# Meat Decision Fallout

- ❑ Lurid headlines linking meat with cancer, akin to smoking
- ❑ Massive Coverage by Wire, Print, Online, Broadcast Media, Blogs
- ❑ More than 1000 articles within the first 24 hours
- ❑ Viral social media chatter



# Meat Decision Fallout



**Ham, Sausages Cause Cancer; Red Meat Probably Does, Too, WHO Group Says**



**Bacon and other processed meats say experts say**

PARIS | BY GUS TROMPIZ

Eating processed meats like hot dogs, sausages or bacon can lead to bowel cancer in humans and red meat is a likely cause of the disease, World Health Organisation (WHO) experts said.



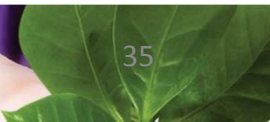
**Processed meats rank alongside smoking as cancer causes - WHO**

UN health body says bacon, sausages and ham among most carcinogenic substances along with cigarettes, alcohol, asbestos and arsenic



**Top stories**

WHO links processed meat, cancer 1 h



# Meat Decision Fallout

**The Washington Post**

**Hot dogs, bacon and other processed meats cause cancer, World Health Organization declares**



For the first time, I'm actually happy to see **#bacon** is trending.  
**#GoVegan** for your health, the planet and the animals.

Retweeted 1,598 times



CNN @CNN · 7h

World Health Organization (@WHO) says processed meat like hot dogs and bacon causes cancer [cnn.it/1O2Gcap](http://cnn.it/1O2Gcap)



1.6K 718

Top news View all

Food Network @FoodNetwork · 17m

A moment of silence for bacon:  
[bit.ly/1kllhM4](http://bit.ly/1kllhM4)

So as well as destroying the planet and causing animals to needlessly suffer, meat can now cause... Well, most of us probably had an inkling. But new evidence today confirms meat-eaters worst fears. Processed foods, such as bacon, sausages and ham, cause cancer.

The Independent Oct 26, 2015

## BuzzFeedNEWS

TRENDING  
220,821 VIEWS



### Bacon And Sausages Do Cause Cancer, Says World Health Organisation

Processed meats are now classed as a carcinogen.

# NCA Q' 1' 2016

## Meat Sales Down 5-20% in IARC Aftermath

Sales of processed meats dropped 10% for Japan's Prima meats after the IARC ruling; hit the traditional year-end gifts which usually include processed meat.

**(Jan 2016) *Prima meat's profit levels off amid weak year-end sales*** <http://asia.nikkei.com/Markets/Tokyo-Market/Prima-Meat-s-profit-levels-off-amid-weak-year-end-sales>

Double-digit decline in processed meat sales were recorded in Israel.

***Months After WHO Warning, Israelis Still Shunning Salami***  
<http://www.haaretz.com/israel-news/business/.premium-1.696869>

Craft butchers in Ireland reported a 20% dip in sausage sales after the publication of the IARC report.

**(December 2015) *Sausage sales (in Ireland) beginning to bounce back from WHO cancer warning***  
<https://www.businesspost.ie/sausage-sales-beginning-to-bounce-back-from-who-cancer-warning/>

**(November 2015) *Meat sales (in Portugal) down 5% after WHO's cancer alert***  
<http://portugalresident.com/meat-sales-down-5-after-who%E2%80%99s-cancer-alert>

Sales of sausages and bacon plunged by £3million in just two weeks in the UK. Sausage sales declined 15,7% and bacon saw a 17% decline in sales.

**(November 2015) *UK shoppers give pork the chop after processed meats linked to cancer***  
<http://www.theguardian.com/uk-news/2015/nov/23/bacon-sausage-sales-fall-who-report-cancer-risk-processed-meat>

Shops in South Korea saw a fall in meat sales ranging from 10%-17.9% in the aftermath of the IARC ruling.

**(October 2015) *Processed meat sales fall after cancer warning***  
<http://koreajoongangdaily.joins.com/news/article/Article.aspx?aid=3010871>

# IARC Review of Coffee

## Present-Day:

- ☐ Coffee is being re-reviewed because a significant number of new studies and reviews have been published on coffee and cancer. Also, a number of evaluations in 1991 were based on limited evidence.
- ☐ Current review of science has concern for: Bladder, kidney, childhood leukemia, and lung.



# Causes for Concern...

- ❑ **Legal:** A 2A Classification triggers automatic listing under Proposition 65 in California
- ❑ **Regulatory:** IARC work products are not intended as rule-making, but can be used to inform rule-making bodies in making diet, health and safety determinations.
- ❑ **Public Relations:** As in the red meat industry, the media will jump on any reports issued by IARC. The coffee industry needs to be prepared to manage any communications that may evolve from the IARC review and report on coffee.
- ❑ **Consumption:** Consumers may not be able to interpret the weight of the scientific evidence. What they hear and associate could impact their coffee consumption behavior



# What can we do as an industry?

- ❑ Be proactive and deliberate. We can be prepared by:
  - ❑ **Knowing the Science** - Conducting a targeted scientific evaluation of the literature on coffee & cancer endpoints. This will help inform:
    - ❑ Industry Observer
    - ❑ Public Relations campaign
  - ❑ **PR Campaign** - Having a robust communications plan

**GOAL:** Be prepared with knowledge on the Science and a Communications and Advocacy strategy so that our industry is not blind-sided or ill-equipped for what could occur.

# Scientific Plan

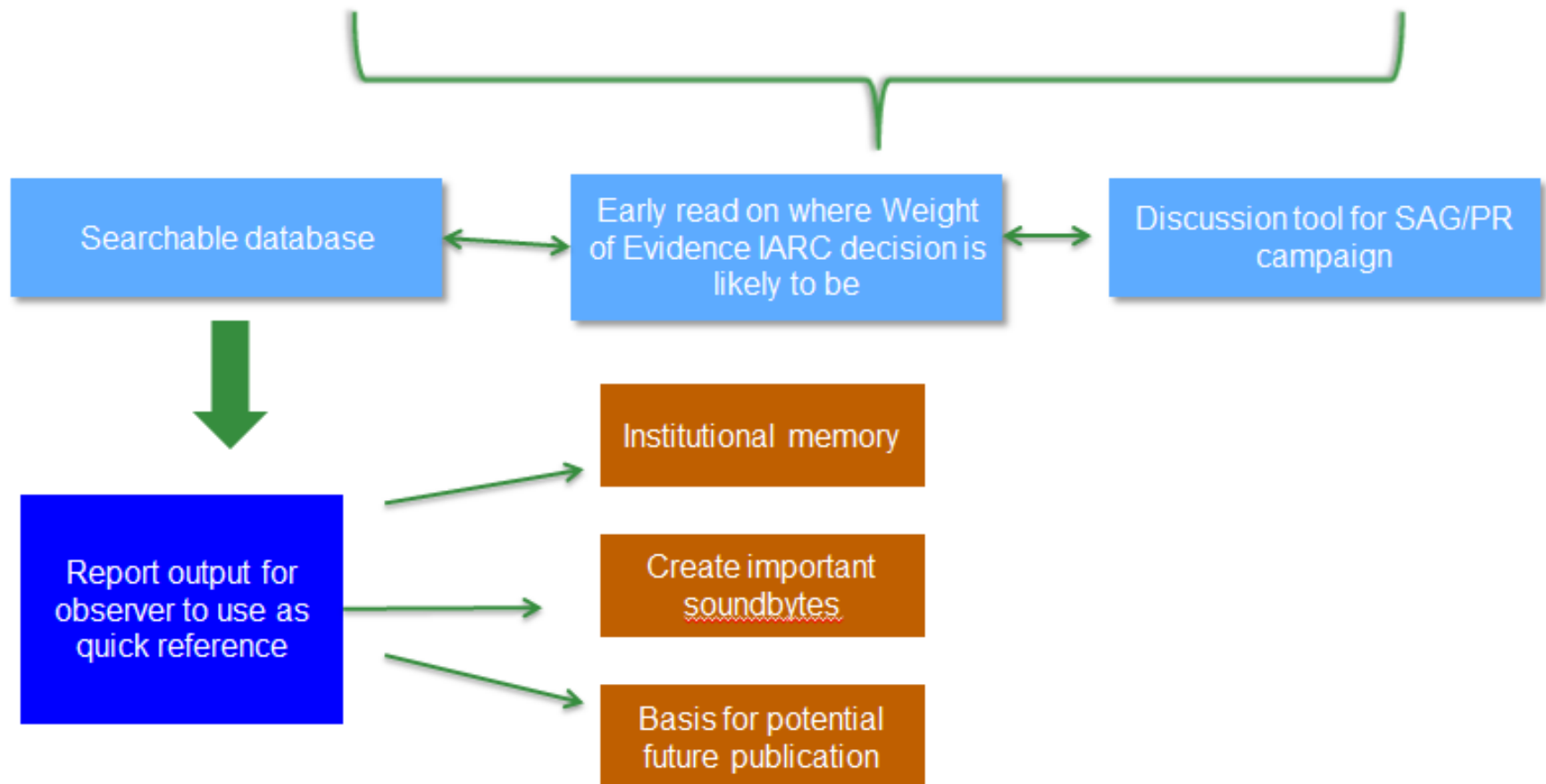
## Four Key Deliverables:

Review literature on bladder/leukemia/kidney

Apply knowledge from other monographs

Factor in expert opinion from JDG

Apply knowledge from mechanistic/"other" categories

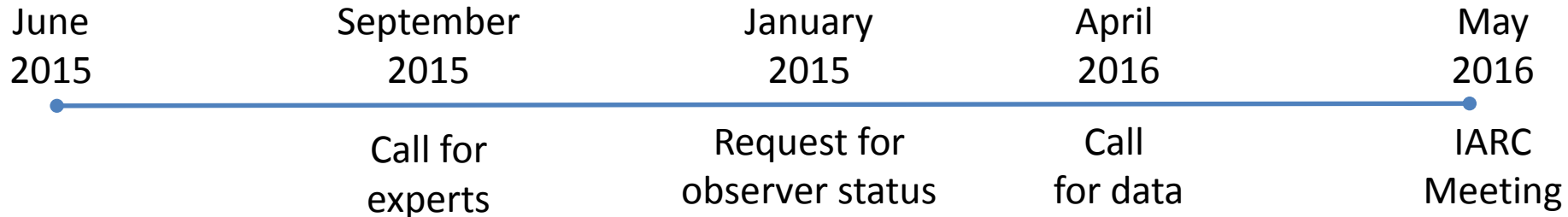


# IARC – Managing Communications

To prepare for a worse case scenario, advance work is occurring to have in place prior to release of the IARC report.

- ☐ Retain a top-notch PR firm with experience managing IARC reviews
- ☐ Compile messaging and research that is “easily digestible” by consumers and media;
- ☐ Identify and arm 3<sup>rd</sup> party experts;
- ☐ Identify, brief and train spokespeople;
- ☐ Create assets including articles, web portals, infographics, testimonials, and other materials for use.
- ☐ Proactively reach out to media with “our story.”

# Timeline



- ☐ Provide key information to inform the process
  - ☐ Critical to provide supporting data (in the peer review literature)
  - ☐ Nominate experts to provide balance
  - ☐ Nominate observers to provide input where appropriate
  - ☐ Perspective on studies
  - ☐ Need to i.d. all studies to be reviewed that need perspective so Industry Observers are prepared & expected outcome is understood

# Coffee & Health



# Coffee & Health

<http://www.ncausa.org/Health-Caffeine>

## Health & Caffeine

Independent research by scientists worldwide continues to link coffee to significant (and surprising) healthful properties.

Coffee has a naturally complex botanical profile, with at least 1,000 natural compounds in the bean (including caffeine) and another 300 created in the roasting process. Scientists have linked a number of them, [including some strong antioxidants](#), with a host of physiological benefits.

Research has shown that moderate coffee consumption (or 3-5 cups daily) may be associated with:

- Liver disease prevention
- Improved cognitive function in older adults
- Sharper memory
- Increased athletic endurance
- Reduced risk of type 2 diabetes
- Longevity

Due to the increasing scientific evidence, coffee has earned a new – and improved – reputation. In fact, the latest U.S. Dietary Guidelines recently made an [unprecedented recommendation](#) for coffee as part of a healthy lifestyle.

### The Caffeine Buzz

Many of these potential benefits are associated with caffeine, a naturally occurring stimulant found in coffee beans. The amount of caffeine in a cup of coffee can vary, depending on factors ranging from the type of bean to how it's brewed.

Caffeinated coffee affects individuals differently, based on heredity, body weight, gender, metabolism (there are “fast caffeine metabolizers” versus slow ones), and coffee drinking habits. While coffee has come to be closely associated with caffeine, consumers can choose from a variety of caffeinated and decaffeinated options.

### LEARN MORE

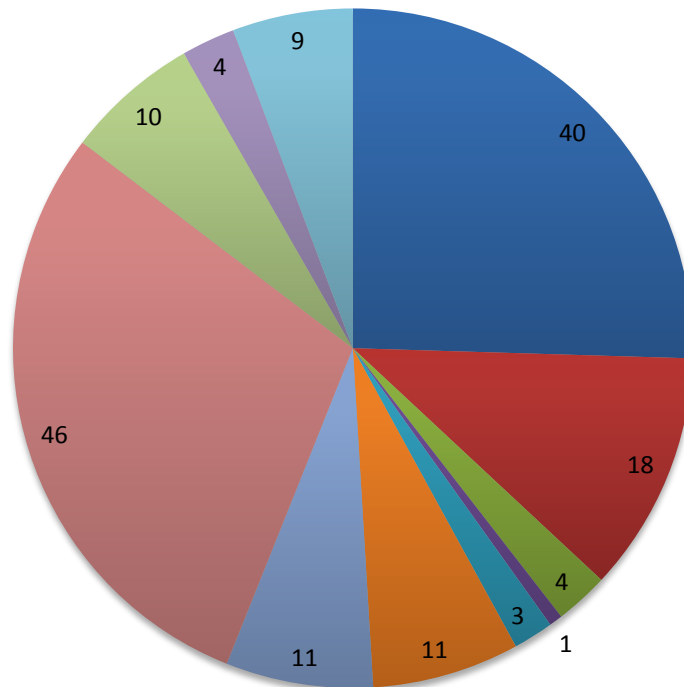
coffee & me

### THE FIRST PULL



# Coffee & Health

## 2015 Literature Tracking Summary January-December (150 articles total)



■ Cancer (40)

■ Cardiovascular Health (18)

■ Chemistry (4)

■ Gallstones (1)

■ Liver Function (3)

■ Mental Performance (11)

