An In-Depth Look at GRAS and Food Ingredient Regulation

Ricardo Carvajal, Director, Hyman, Phelps & McNamara, PC

Dennis Keefe, Director, Office of Food Additive Safety, CFSAN, FDA **Mark Mansour**, Partner, Locke Lord LLP

FDA's Food Additives Program

Dennis Keefe, PhD
Director
Office of Food Additive Safety

FDA's Food Additives Program

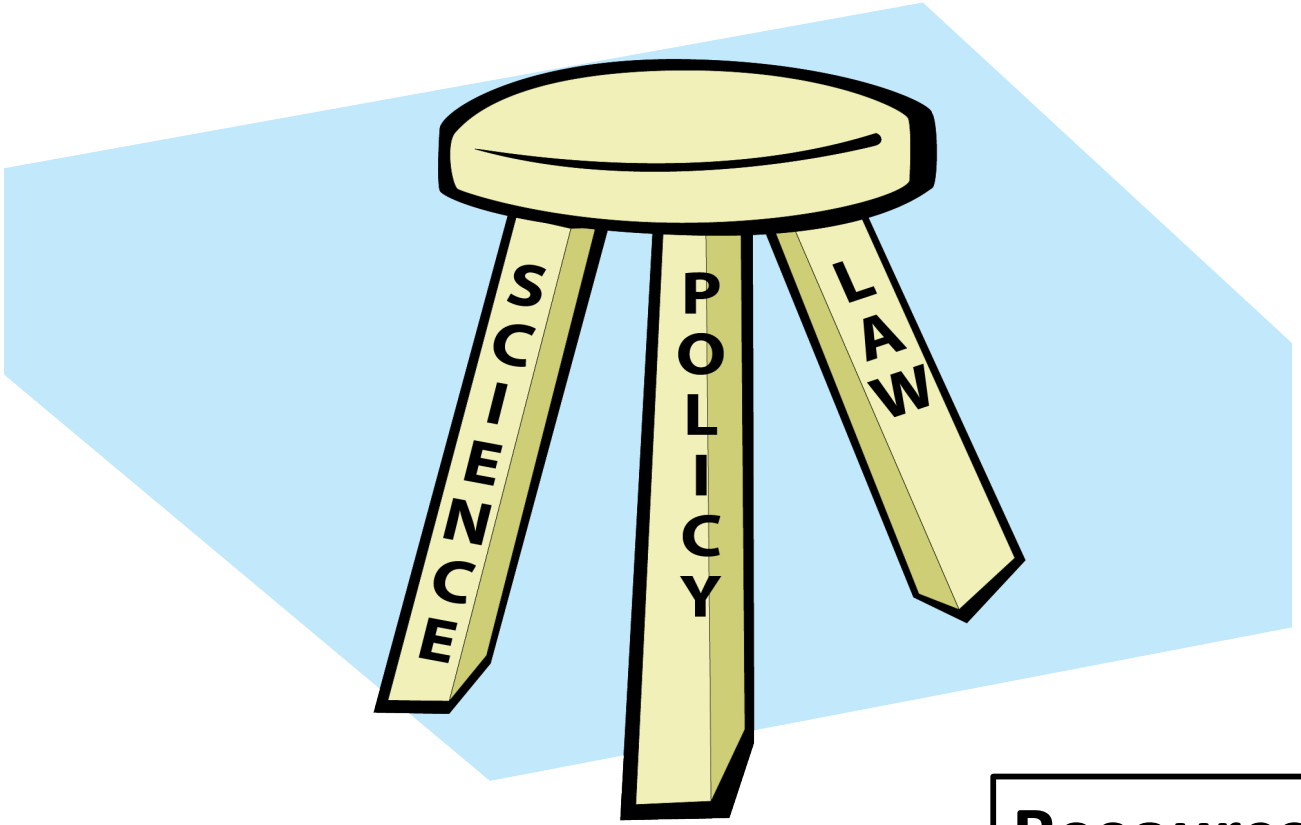
MISSION STATEMENT

To protect and enhance consumer health by ensuring the safety of substances added to food and food contact materials.

FDA's Food Additives Program

VISION STATEMENT

OFAS is the world leader in applying sound science to food safety decisions and supporting and developing an exceptional workforce to serve the public.



Resources?

FDA's Food Additives Program

FFDCA – Key Sections

- Food Additive Definition – 201(s)
  - Includes GRAS criteria
- Color Additive Definition – 201(t)
- Food Contact Substance Definition - 409(h)
- Food Additive Petition Process – 409
  - 409(c)(3) – Delaney Clause
- Color Additive Petition Process – 721
  - 721(b)(5)(B) – Delaney Clause

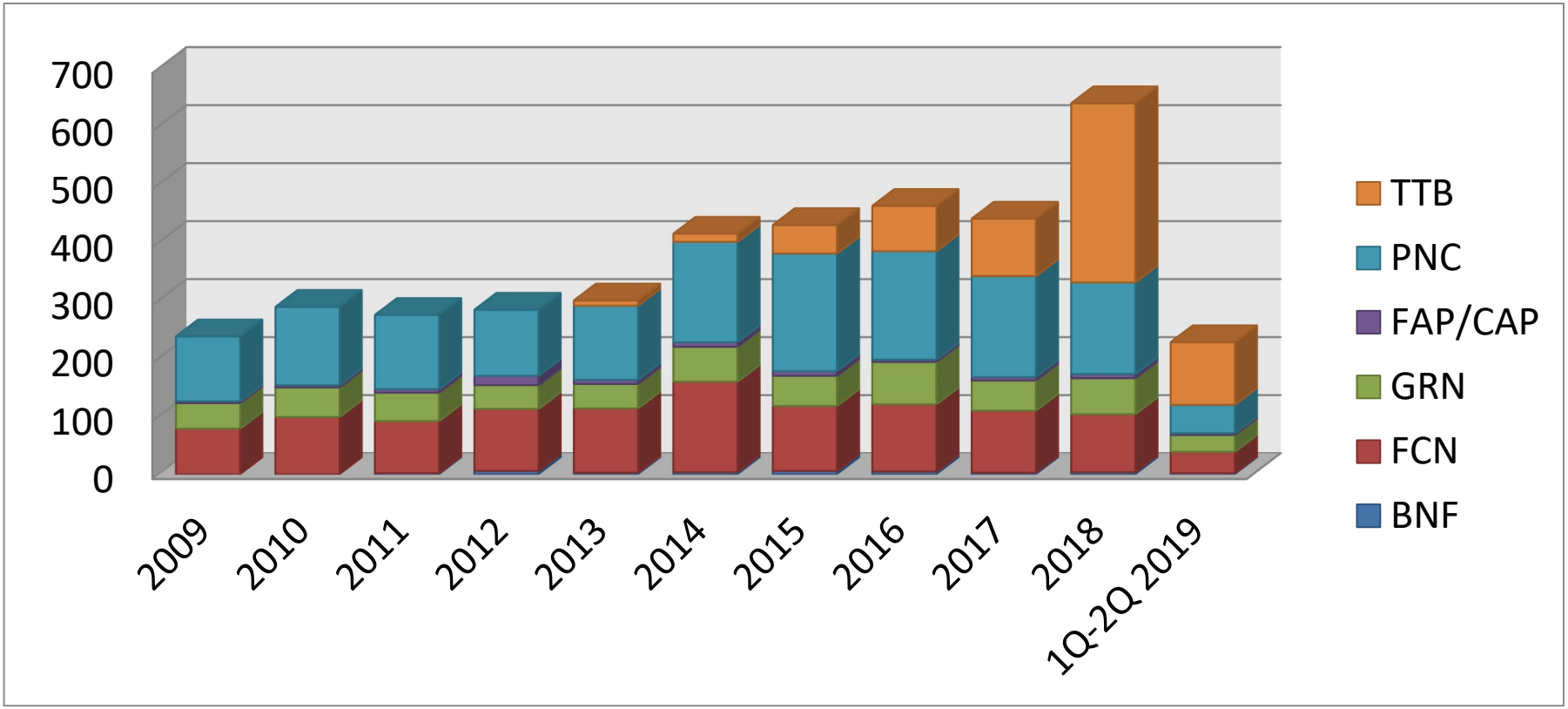
How We Regulate

Premarket Programs

Petition Process	GRAS Notice	Food Contact Notice	Biotech Consultation
FAPs since 1958 CAPs since 1960	1997 to present	1997 to present	1992 to present
Mandatory	Voluntary	Mandatory	Voluntary
Sponsor submits a petition asking FDA to issue a regulation	Sponsor informs FDA of their view that a use of a substance is GRAS	Sponsor submits a notification	Sponsor informs FDA of their view that foods derived from the new plant variety are safe
FDA owns the safety decision	Sponsor owns the safety decision; FDA evaluates the their basis	FDA owns the safety decision but there is a 120-day "hammer"	Sponsor owns the safety decision; FDA evaluates their basis
FDA publishes a regulation	FDA responds by letter (no questions, no basis, withdrawal)	FDA responds by letter (deficiency, effective, objection)	FDA responds by letter
No exclusivity	No exclusivity	By law, exclusive to manufacture or supplier	
Petition is available publicly through FOIA	GRAS Notice & FDA's response are on FDA's website	FDA maintains a database of effective notifications on its website	BNFs & FDA's response are on FDA's website
90 + 90 = 180 Days	180 + 90 = 270 Days	120 Days	Not Specified

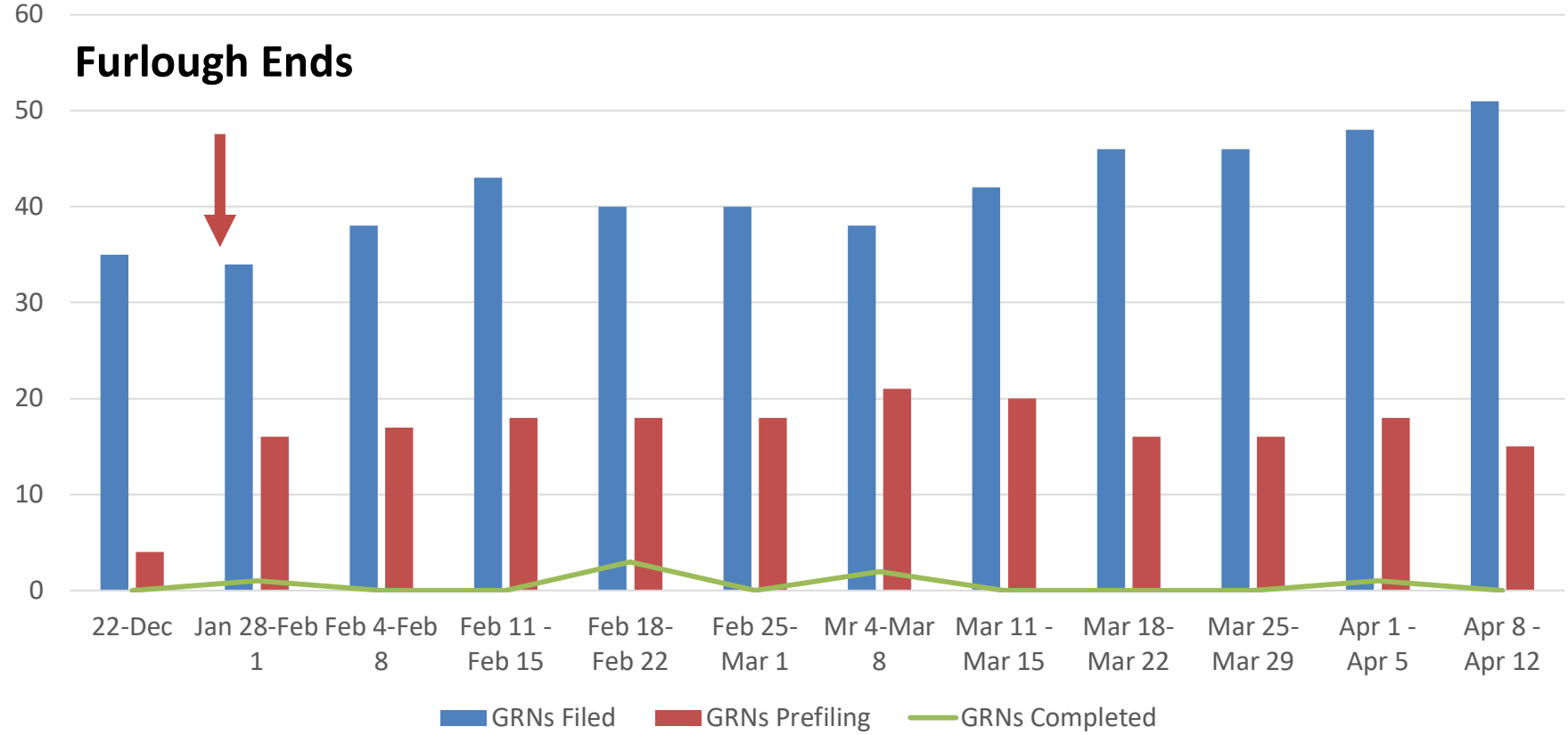
Accomplishments by Fiscal Year

All Submissions Completed (2009-2019)



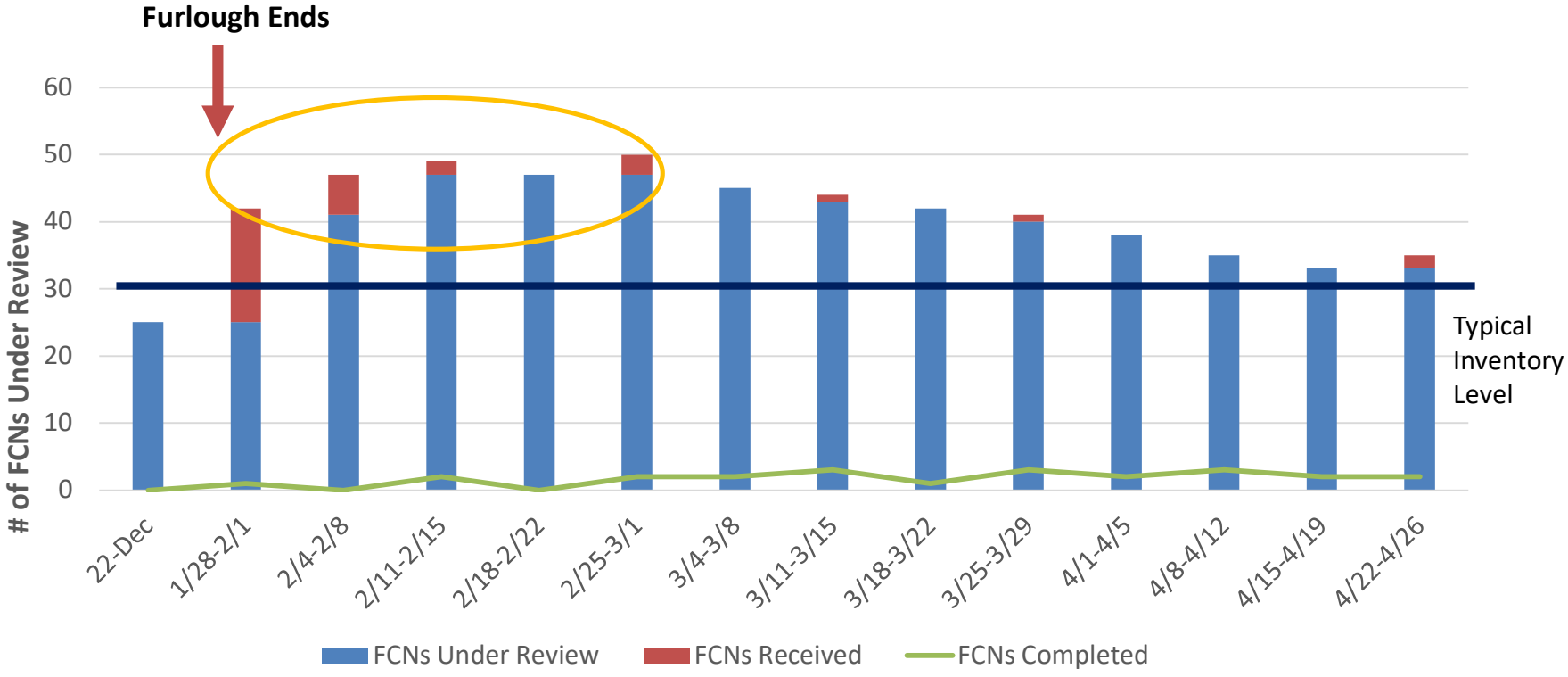
2018/2019 Furlough

Status of GRAS Notices



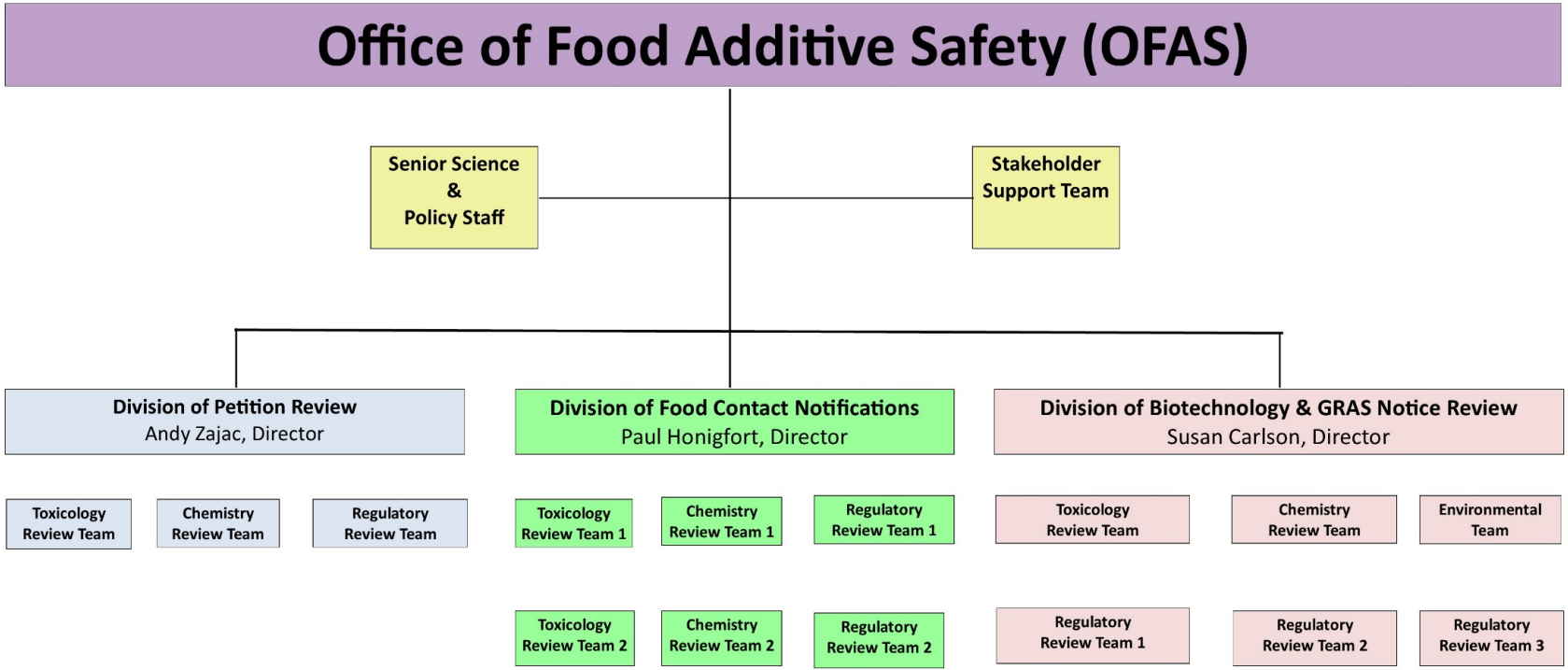
2018/2019 Furlough

Food Contact Notifications



FDA's Food Additives Program

Current Organization



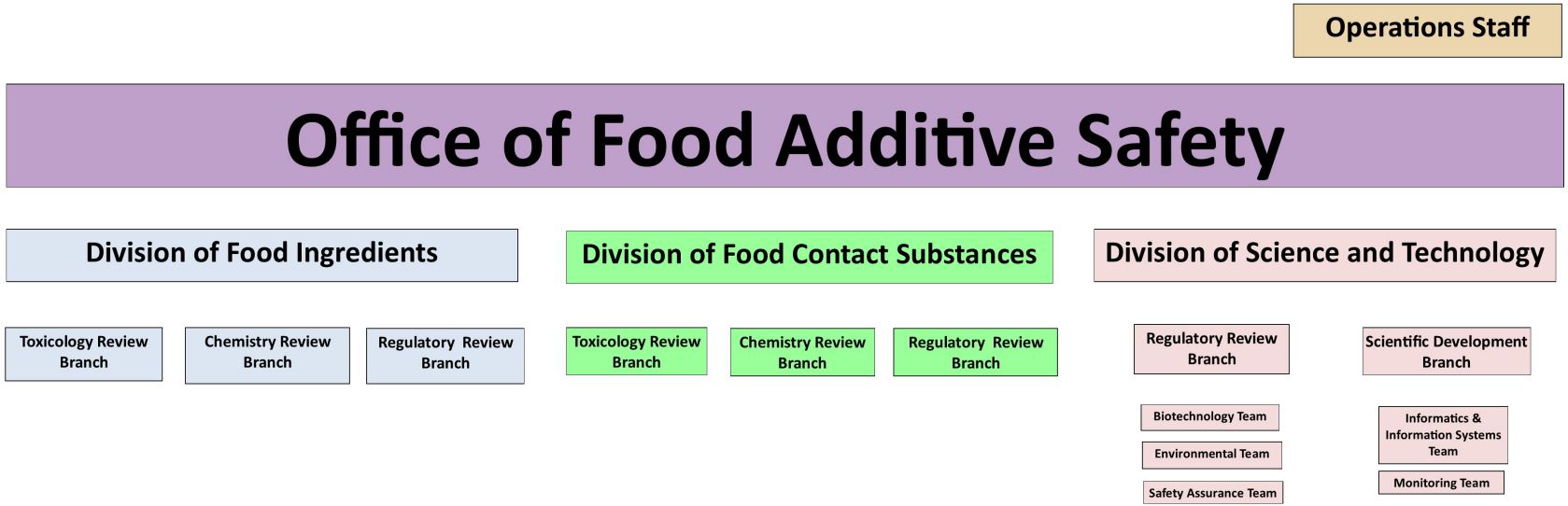
FDA's Food Additives Program

What Has Changed?

- Workload
- Science
- Food Technology
- New Data Streams/Information

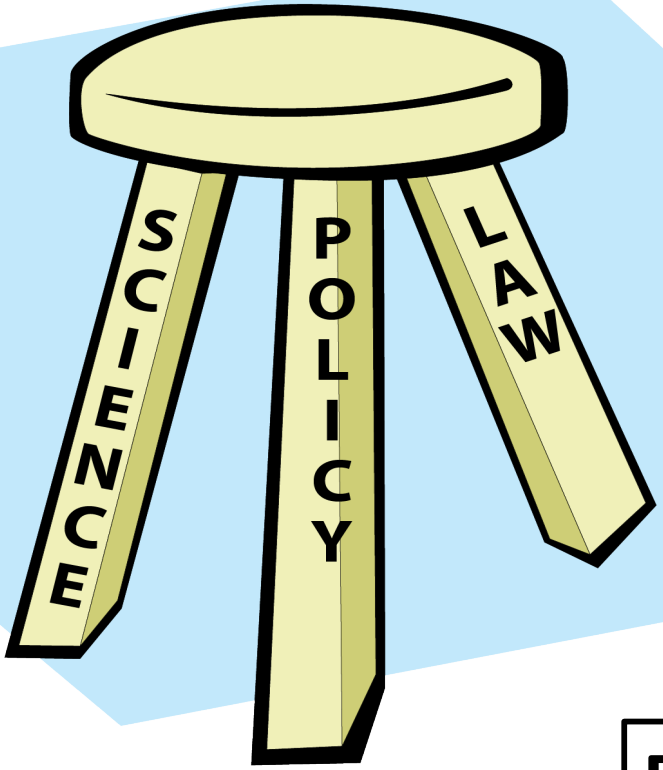
FDA's Food Additives Program

New Organizational Structure



Challenges

- Workload
- Scientific Advances
- Food Technology Innovations
- New Data Streams
- Other?



Resources?

Divergent Perspectives on GRAS

Mark Mansour
Locke Lord LLP
mark.mansour@lockelord.com
(202) 220-6958

Ricardo Carvajal
Hyman, Phelps & McNamara PC
rcarvajal@hpm.com
(202) 737-4586

Increased Oversight vs Self-Regulation

- What is the proper level of regulatory review for the addition of new uses of ingredients to the food supply?
- Should there be different standards for novel substances/novel foods?
- Would mandatory notification require a statutory amendment?
- Does the current system present safety concerns?

The Importance of Consumer Confidence

- Are potential conflicts of interest a problem, and is FDA's guidance on the subject an adequate fix?
- Should consumers expect premarket review of all new uses of substances – and would they be willing to pay for it?
- Would increased voluntary participation in the GRN program help, and how could it be achieved?

Should FDA Do More Under its Existing Authority?

- Could/should FDA take more enforcement actions against domestic and imported products?
- Could/should FDA review GRAS determinations during routine inspections?
- Should FDA require specific tests as part of safety evaluations (e.g., animal testing?)

What Might a Mandatory Premarket Review Program Look Like?

- Petition requiring approval (e.g., FAP) vs notification that is authorized absent objection (e.g., FCN)
- FDA determination vs FDA review of company's determination
- User fee funding vs general appropriation