PROTEIN TRENDS & TECHNOLOGIES SEMINAR

The Food Industry's Current and Future Regulatory Environment

Jessica P. O'Connell
jpoconnell@cov.com
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Overview

Key Question: How will they interact to effect regulatory change?

Agenda

- Key Trump Administration Orders
- FDA Expectations and Impact
- USDA Expectations and Impact
- Questions?

Major Food Regulatory Developments Since May 2016

- FDA final rule updating the Nutrition Facts label
- Federal bioengineering disclosure law enacted, preempts VT & others
- FDA draft guidance on the FSMA preventive controls rule (first 5 chapters released)
- FDA final rule on GRAS substances and notifications
- FDA draft guidance on NFL final rule – added sugars, etc.
- FDA NDI updated draft guidance

**Nothing broadly relevant issued since January 2017

Key Trump Administration Orders

- **Regulatory Freeze Pending Review – 1/20/17**
  - directed all federal agencies to implement a freeze on "new or pending" federal regulations to provide the administration an opportunity for review
  - "regulation" includes "any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking," *and* guidance documents and any other agency statement "that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue"
  - USDA GE ANPRM – withdrawn from OMB review post-freeze (even though statutory deadline)

Key Trump Administration Orders

- **Reducing Regulation and Controlling Regulatory Costs – 1/30/17 [“2 for 1” order]**
  - states, in relevant part: “[I]t is important that for every one new regulation issued, at least two prior regulations be identified for elimination. . . .”
  - OIRA guidance: in Fiscal Year 2017 the order will only apply to new “significant regulatory actions”
- **Enforcing the Regulatory Reform Agenda – 2/24/17 [implementing “2 for 1” order]**
  - each agency must evaluate existing regulations and make recommendations to the agency head regarding their repeal, replacement, or modification, consistent with applicable law
  - stakeholders should have the opportunity to interact with these agencies and offer input concerning potential “regulations” for repeal, replacement, or modification

Key Trump Administration Orders

- **Enforcing the Regulatory Reform Agenda – 2/24/17 [implementing "2 for 1" order]**
  - focus on regulations that:
    - **eliminate jobs, or inhibit job creation**;
    - are **outdated, unnecessary, or ineffective**;
    - **impose costs that exceed benefits**;
    - create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;
    - are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), or the guidance issued pursuant to that provision; or
    - derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified

Key Trump Administration Orders

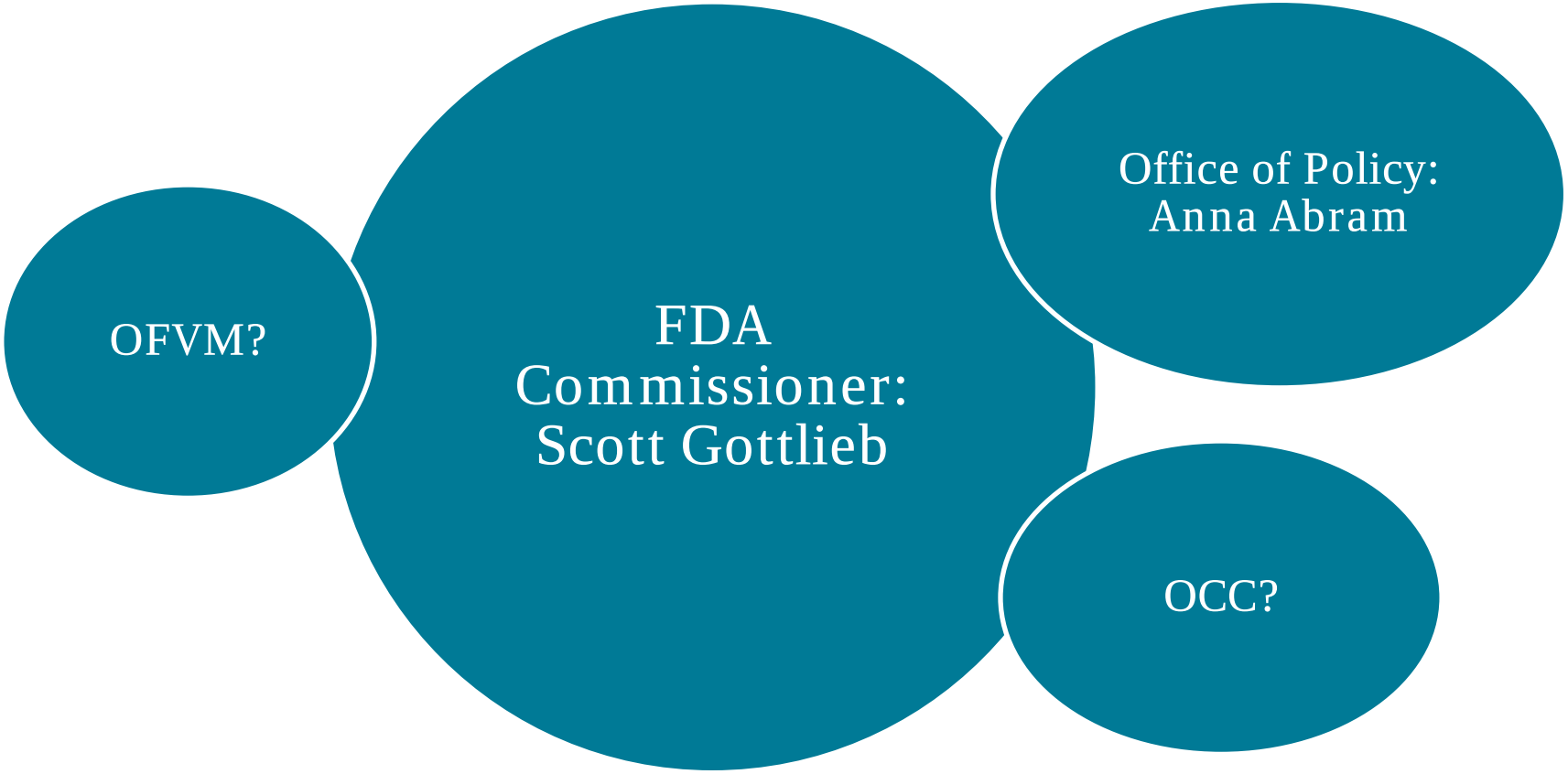
What does this mean in practice?

- Agencies must consider executive orders when undertaking rulemaking and other regulatory action
- What will be eliminated?
- What is a “regulation”? Does it include guidance?
- What about new rules or actions that reduce costs?

FDA Expectations and Impact

- New Commissioner
- Nutrition Labeling Final Rule
- “Follow on” nutrition labeling updates
- Dietary ingredients
- FSMA implementation

FDA Expectations and Impact



FDA Expectations and Impact

"Remarkably unremarkable" confirmation hearings in March.

Dr. Gottlieb said he would favor delay in Nutrition Facts update deadlines

Current deadline is July 2018 if food sales exceed $10 million

- to line up with developments on USDA GMO labeling rule label change deadlines
- Estimated to cost up to $4.6 billion with current deadlines

FDA Expectations and Impact

Nutrition Labeling Final Rule

- Current compliance date: July 26, 2018 [non-small business]
- Critical issues: Dietary fiber; Added sugar; Recordkeeping
  - Lack of final guidance?
  - Business considerations – contracting timelines
  - Potential for change?

Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

FDA Expectations and Impact

"Follow on" Nutrition Labeling Updates

- Nutrient Content Claim updates
- Health Claim updates
- "Natural"
- "Healthy"

Dietary Ingredients

- Revised NDI Draft Guidance – August 2016
  - Reiterated most principles from prior version
  - Key issues:
    - When is notification required?
    - What is modification?
    - Who must notify?
  - Expectations for next 4 years?

FDA Expectations and Impact

FSMA Implementation

- All foundational final rules published
- Staggered compliance dates for each rule
- Limited guidance in place
- Implementation beyond “foundational” rules?
- Resources?

USDA Expectations and Impact

GE Labeling Implementation

- Law enacted July 29, 2016; **deadline** of 2 years after enactment
- Directs USDA to establish a national mandatory bioengineered food disclosure standard within two years of enactment
  Requires USDA to issue regulations, but does not set a date by which the regulations must be finalized
- Preempts the "produced with genetic engineering" labeling provisions of Vermont Act 120 and the enactment or enforcement of similar provisions in other states
- ANPRM sent to OMB early 2017 – withdrawn under "regulatory freeze"

USDA Expectations and Impact

GE Labeling Implementation

- Bioengineered food: A food is considered to be bioengineered if:
  it ***contains*** genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and the modification could not otherwise be obtained through conventional breeding or found in nature

- Does not appear to apply explicitly to foods such as highly refined oils/starches that were made from a GE source but in which there is no GE protein present in the oil/starch
- The statute expressly exempts animal-derived products where the animal was fed bioengineered feed but was not bioengineered

USDA Expectations and Impact

GE Labeling Implementation

- USDA must "establish a process for requesting and granting a determination by [USDA] regarding other factors and conditions under which a food is considered a bioengineered food"

- Does not define "non-GMO" or equivalent *but* exemption for "organic"

- Food manufacturers may select from the following on-package disclosure options:
  - Text;
  - A symbol; or
  - An electronic or digital link

Questions?

Jessica P. O'Connell
Covington & Burling LLP
(202) 662-5180
jpoconnell@cov.com