

Food Contact Substance Notification Program

FY 2009 Update

October 21st, 2009
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Division of Food Contact Substance Notifications
Office of Food Additive Safety

Center for Food Safety and Applied Nutrition
Food and Drug Administration

Today's Agenda

- Organizational Chart
- Program Statistics
- Post-Market Evaluations
- On-Going Projects

FDA Organization

Office of the Commissioner



Office of the Center Director

Stephen Sundlof, DVM, PhD

Office of Compliance
Office of Regulatory Science
Office of Management Systems
Office of Cosmetics and Colors
Office of Regulations Policy and Social Sciences
Office of Applied Research and Safety Assessment
Office of Nutrition, Labeling, and Dietary Supplements
Office of Food Defense, Communication and Emergency Response
Office of Food Safety
Office of Food Additive Safety
CFSAN Staff College

Direct -vs- Indirect Food Additives

Direct

Intentionally added to food

Technical effect in food

Title 21 CFR 172 & 173

Food Additive Petition Process

Indirect

Not intended to become a component of food

No intended technical effect in food

Title 21 CFR 174 – 179 and FDA's FCN Inventory

Food Contact Substance Notification Process

Petition -vs- FCN

Petition

Direct Food Additives only

Manufacturer petitions FDA for a new regulation

Petition must demonstrate proposed use is safe

Becomes effective after FDA promulgates a rule

Listed in Code of Federal Regulations

Food Additive regulations are generic

FCN

Additives with no technical effect in food

Manufacturer notifies FDA of intent to market a new FCS

Notification must demonstrate proposed use is safe

Becomes effective after 120 days, unless FDA objects

Listed on FDA Inventory

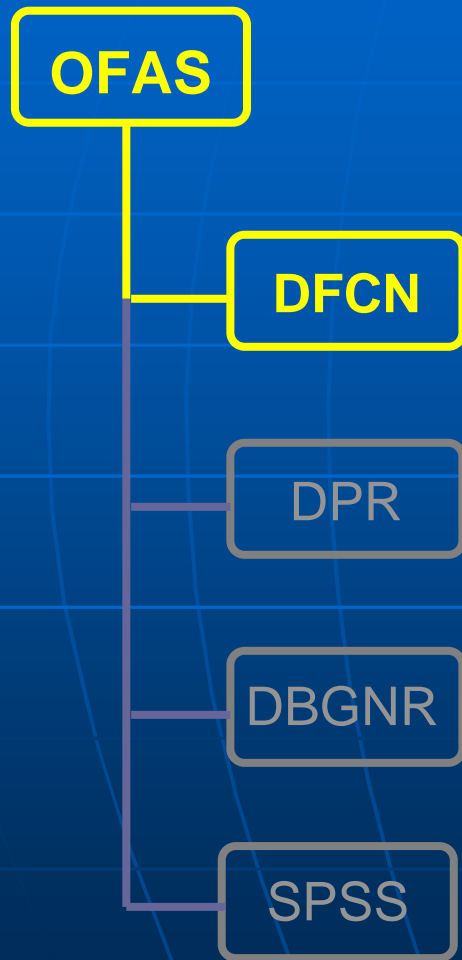
Notification is effective only for Notifier

OFAS Responsibilities

- Food Contact Substance Notification
- Food Additive Petitions
- Biotech and GRAS Notices
- Environmental Impact of OFAS Decisions

- **FAO/WHO Codex Alimentarius**
 - Food Additives Standard
 - Guidelines & Codes of Practice
- Post-Market Monitoring of Additive Issues

OFAS Organization

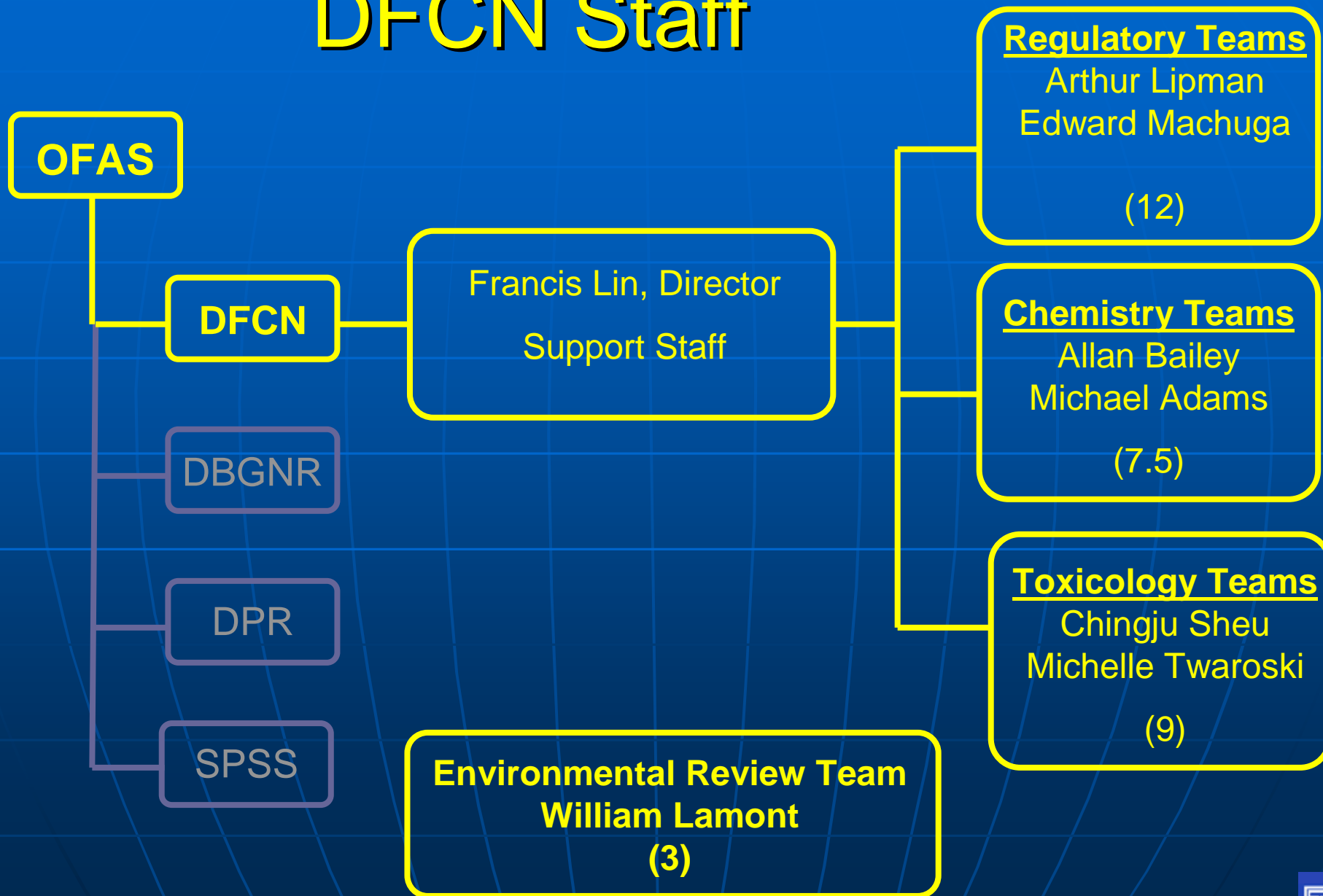


DFCN Responsibilities

- Food Contact Substance Notifications
- pre-Submission Consultations

- Threshold of Regulation Submissions
- Food Additive Petitions
 - Cumulative exposure ≥ 1 mg/kg (biocides ≥ 200 $\mu\text{g}/\text{kg}$)
 - Bioassay data exists that
 - FDA has not yet reviewed; and,
 - Is not clearly negative for carcinogenic effects
- Requests for Information

DFCN Staff



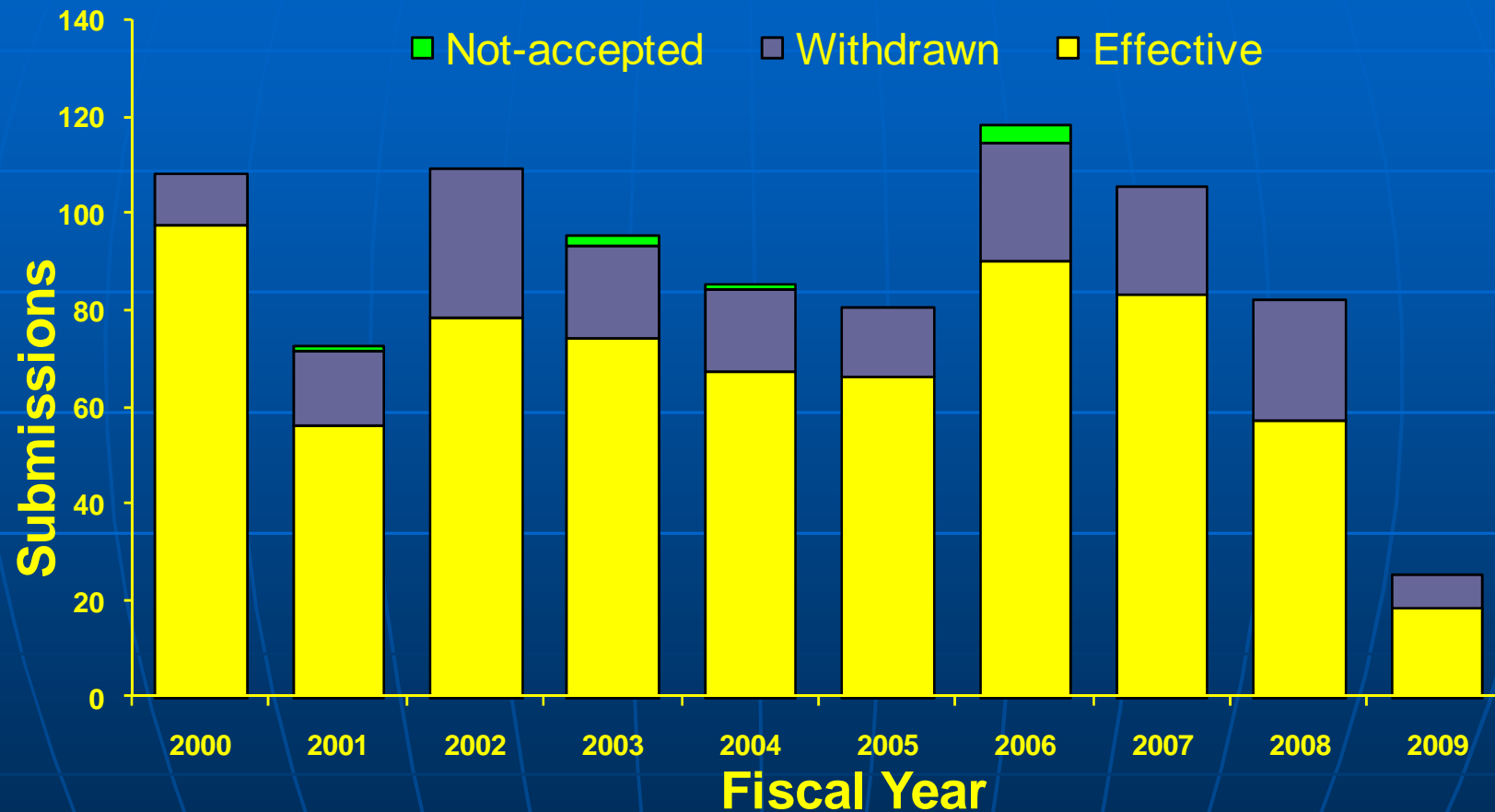
FCN Program is 10 Years Old!!

- Food & Drug Admin Modernization Act - 1997
- Developed Procedural Regulations
- Funded and Operational in FY 2000
- First 66 FCNs were Food Additive Petitions



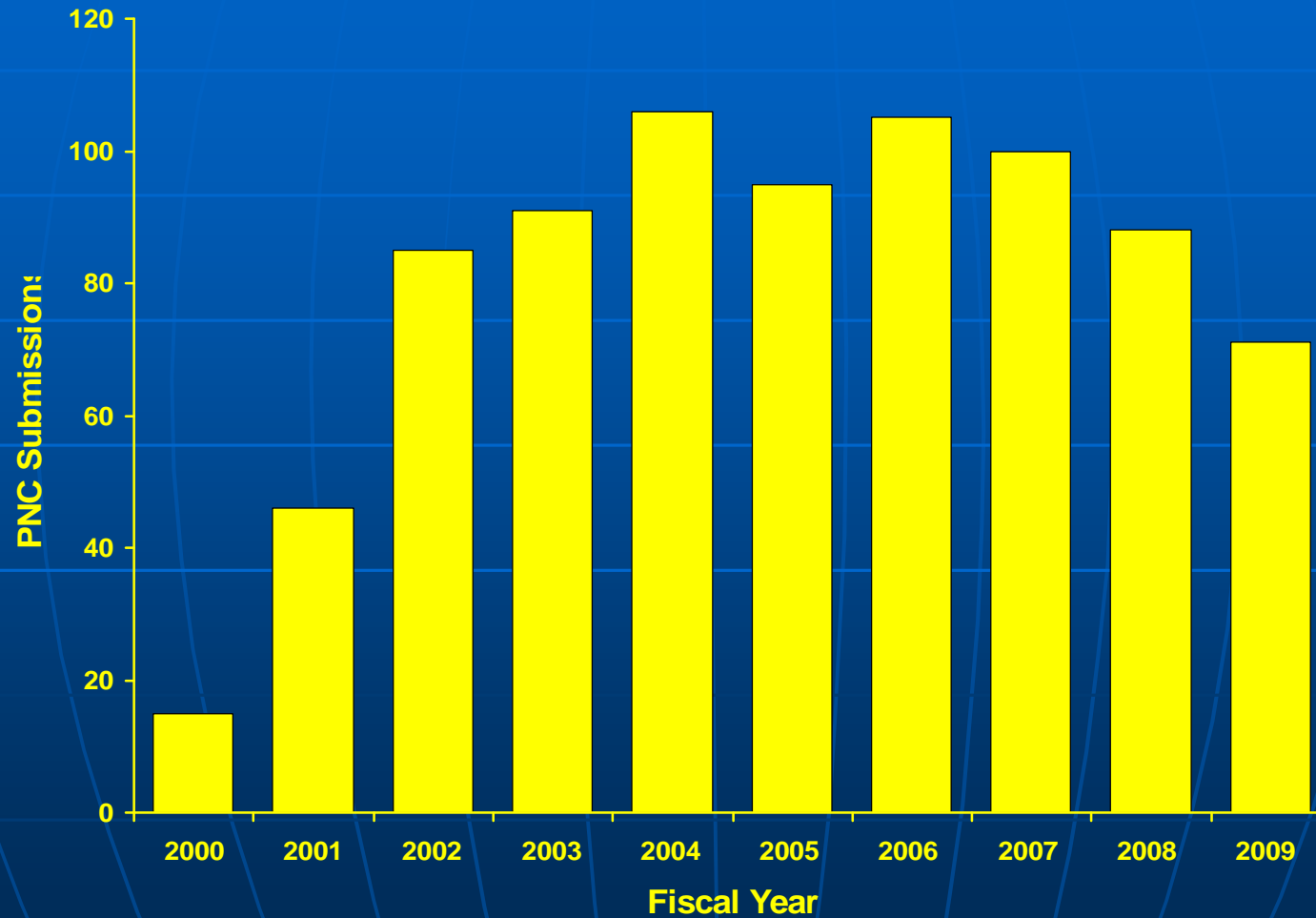
Food Contact Notifications

Total = 879



Pre-Submission Consultations

Total = 802



Post-Market Evaluation Bisphenol A

A monomer used to manufacture polymers for

- Epoxy based can coatings
 - infant formula cans
 - baby food jars
 - canned foods
- Polycarbonate bottles
 - nursing bottles
 - sippy cups
 - water bottles and carboys

Post-Market Evaluation Bisphenol A

- Endocrine Active Compound
- Some studies suggest low-dose effects
 - Mammary Gland Cancer
 - Prostate Gland Cancer
 - Neuro-Developmental Effects
 - Early Onset of Puberty in Females

Bisphenol A Timeline

August 14, 2008

FDA Draft Assessment of Bisphenol A for Use in Food Contact Applications

September 16, 2008

BPA Subcommittee held a public meeting:

Food and Drug Administration on methods employed;

National Toxicology Program on approach used for NTP assessment;

Chapel Hill Bisphenol A Expert Panel on conclusions of their review; and,

Public comment.

October 31, 2008

FDA Science Board accepted the report of the Subcommittee

August 31, 2009

CFSAN to complete review of Low-dose studies identified in Science Board Report

October 21, 2009

External review of Low-Dose Study report by non-FDA Federal Scientists

November 30, 2009

Commissioner will review science and safety standard and decide on how to proceed

If safety standard is met, FDA will explain basis of findings, and advice;

If safety standard is not met, FDA will announce plans to initiate rule making.

Post-Market Evaluation Phthalates

- Used as polymeric plasticizers
- Endocrine Active Compounds

- FDA Task Force on Phthalates established in 2008
 - On-going post-market review of phthalate containing Food Contact Substances

Post-Market Evaluation Perfluoro & Siloxanes

Perfluoro Compounds (*grease proofing agents*)

- Aware of studies indicating potential to persist & cause low dose toxicity
- FDA recommendations for FCN do not address these issues
- Working with stakeholders to investigate exposure and toxicological properties
- Special considerations for migration testing of perfluoro compounds

Siloxane Compounds

- Another group of endocrine active compounds and suspected carcinogens
- On-going post market review of exposure and toxicity

FDA recommends consulting with the Agency before preparing an FCN relating to these classes of compounds

On-Going Projects

Nanotechnology

- Materials consisting of particles on a size scale of approximately 1 - 100 nanometers
- Have novel properties and functions due to their size
- Concern that these small particles may be able to cross membrane barriers in the body and produce toxic effects
- Collaboration with NCTR – genetic toxicity testing
- Collaboration with stakeholders – overall testing methodology

On-Going Projects

- **Web Site** www.fda.gov
 - Redesigned to meet usability standards
 - Hierarchal structure based on products (e.g. foods, or colors)
 - Foods section – Food Ingredients and Packaging
 - Current inventory listings appear in a data query format
 - URLs have changed
 - FOIA information may contain outdated URL information

Summary

Organizational Structure

Organization Chart

Program Statistics

Graphs of DFCN Productivity

Post-Market Evaluations

Bisphenol A

Phthalates

Perfluoro & Siloxanes

On-Going Projects

Nanotechnology

Web Site

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