Public Health and Tobacco Policy Center

Ways & Means

Participatory Rulemaking: A Guide to Locating and Commenting on Proposed Federal Regulations

Public Health and Tobacco Policy Center

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The Public Health and Tobacco Policy Center is a resource for the New York Department of Health. It is funded by the New York State Department of Health and works with the New York State Tobacco Control Program, the New York Cancer Prevention Program, as well as the programs' contractors and partners to develop and support policy initiatives that will reduce the incidence of cancer and tobacco-related morbidity and mortality.

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Notice and Comment Rulemaking

Introduction

Did you know you have the ability to influence federal regulations? You do!

In fact, the "notice and comment" rulemaking process that federal agencies use *relies* on public input. As the name implies, an agency must **give public notice** of its proposed rule and then **solicit public comment** on that proposal. Anyone with relevant experience, knowledge or opinions on the proposed agency action, including how it may be improved and why it should remain in its current form, may contribute comments. The agency is obliged to consider each sound contribution and explain the outcome. Public submissions and agency analyses are recorded in and available for public and judicial review. Widespread input on the draft rule is important: it helps ensure an agency has weighed diverse perspectives and research and should thus result in a more effective final regulation. Because federal agencies are not comprised of elected individuals, the public's opportunity to influence legislation and hold government accountable stems from the notice and comment rulemaking process and is therefore integral to our democratic process.

Purpose of this Guide

As an educator of tobacco control measures, you have firsthand experience with these issues and serve as the agency's eyes and ears on policy efficacy, practicality, feasibility and more. Your input on relevant regulations is not only valuable, it's vital. Through notice and comment rulemaking, you can review proposed rules and share your insights with regulators by submitting a comment.

This guide outlines the purpose and process of notice and comment rulemaking. It intends to familiarize the reader with relevant federal government publications and requirements, as well as how the public may submit comments on a proposed federal rule. The guide includes steps detailing how to:

- find a proposed rule of interest in print and online;
- submit a comment on a proposed rule by U.S. Mail and the internet;
- craft a relevant comment easily linked to the proposed rule;
- track a submission and verify the agency has reviewed it.

How does an agency provide "notice" of a proposed rule?

- Federal agencies publish proposed rules in the government's daily newspaper, called the Federal Register.[1] The Federal Register is published in print and on the internet.
- Through publishing the proposed rule in the Federal Register, an agency has satisfied its requirement to give "notice" to the public of upcoming regulations. Most agencies will also announce the existence of their proposed rule on its website and through email to recipients registered for such updates.
- These proposed rules are published for public input and are not final rules; accordingly, they are not in effect and are not enforceable. An agency must complete the required rulemaking process, including seeking and evaluating public comments, before a rule becomes binding.

What is Federal "comment"?

- A proposed agency rule is published to allow the public opportunity for input on the rule. When this written input is submitted to the agency, it is considered a "comment" and becomes part of the agency's official record.
- A comment may be formal or informal; based on research, **experience and/or observations**; on behalf of a group or individual or anonymous.[2] The purpose is to explain which aspects of a proposed rule you agree or disagree and the support for your position. Including your relevant education, training or experience may increase the value of your comment. Comments may include policy alternatives or language changes and their rationale, such as explaining how your suggestions would strengthen the final rule and/or the agency objective.
- Comments on proposed rules are accepted during a defined time period, beginning with the rule's publication in the Federal Register. (Note, comments on requests for guidance documents may be submitted even after the guidance is finalized.)
- This announcement and posting includes details on how comments may be submitted and when the comment period ends.[3] In some instances the agency might hold a hearing wherein oral comments from interested and affected parties are presented.[4]
- Agencies are not required by law to maintain the comment period for a specific amount of time, but rather are required to provide a public comment period of "not less than 30 days before [the rules] effective date."[5] Since comment periods vary, interested parties should check the announcement reporting the comment period for the regulation of interest.
- All written and oral comments become part of the rulemaking record.[6]
- Neither federal law[7] nor New York law considers commenting a form of lobbying.[8]

What happens after "notice and comment" is complete?

- After the comment period closes, the agency must consider all submitted comments and hearing testimony. The agency may choose to revise the rule in light of the feedback.
- If the agency significantly changes the initial rule, there must be an additional public comment period and the above process is repeated.[9]
- Once the agency has finalized the rule, it publishes this "final rule" in the Federal Register and sets a date for the rule to go into effect.[10]
- The final rule is then added to the Code of Federal Regulations.[11]
- A record of the entire process, including summaries of all submitted comments and the agency's decision regarding these comments, is created and is publically available in the Federal Register.[12]
- A rule could be challenged based on several things, including claims that it was passed "without observance of [agency] procedure required by law; unsupported by substantial evidence... or unwarranted by the facts..."[13] The official record serves to document that there is strong basis in facts and evidence for the final rule. It also documents the process undertaken by an agency and may be reviewed by a judge if the legitimacy of that process is challenged.

Step One – Finding Proposed Rules

There are several ways to learn of proposed rules calling for public comment:

a. The Federal Register
b. Regulating Agency Website
c. Regulations.gov

The Federal Register

The Federal Register is published daily online and in print and lists all Federal agencies' proposed rules, alongside newly implemented rules.

Included in the announcement is the duration of the public comment period. Comments on proposed rules must be submitted before the **comment period** closes.

The print edition organizes the regulations by overseeing agency (listed alphabetically). [Note FDA is an agency within Dep't of Health & Human Services.] The website may be searched several ways, including by agency (e.g., "FDA"), topic (e.g., "tobacco") and current proposed rules.

Subscribe to Federal Register notifications; choose notifications pertaining to an agency, topic or personalized search results.

Federal Register / Vol. 76, No. 175 / Friday, September 9, 2011 / Proposed Rules 55835

er 16, 2011, from 9 a.m. om 8E–089. The g agenda includes greement on facilitator cedure, presentations ltants on the results of lysis of alternative candidate standard levels, and identification of the issues to be addressed by the negotiations, and any outstanding data needs.

Public Participation: Members of the public are welcome to observe the business of the meetings and to make comments related to the issues being discussed at appropriate points, when called on by the moderator. The facilitator will make every effort to hear the views of all interested parties within limits required for the orderly conduct of business. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, e-mail *erac@ee.doe.gov* no later than 5 p.m., Thursday, September 8, 2011. Please include "MV Work Group 091511" in the subject line of the message. An early confirmation of attendance will help facilitate access to the building more quickly. In the e-mail, please provide your name, organization, citizenship and contact information. Space is limited.

Anyone attending the meeting will be required to present government-issued identification. Foreign nationals will be required, per DOE security protocol, to complete a questionnaire no later than one week prior to the meeting, Thursday, September 8, 2011.

Participation in the meeting is not a prerequisite for submission of written comments. ERAC invites written comments from all interested parties. If you would like to file a written statement with the committee, you may do so either by submitting a hard or electronic copy before or after the meeting. Electronic copy of written statements should be e-mailed to *erac@ee.doe.gov*.

Minutes: The minutes of the meeting will be available for public review at *http://www.erac.energy.gov*.

Issued in Washington, DC, on August 29, 2011.

LaTanya R. Butler,

Acting Deputy Committee Management

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1140

[Docket No. FDA–2011–N–0467]

RIN 0910–AG43

Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information related to the regulation of non-face-to-face sale and distribution of tobacco products and the advertising, promotion, and marketing of tobacco products. FDA is taking this action as part of its implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA is requesting comments, data, research, or other information related to non-face-to-face sale and distribution of tobacco products; the advertising, promotion, and marketing of such products; and the advertising of tobacco products via the Internet, e-mail, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients.

DATES: Submit either electronic or written comments by December 8, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0467 and/or RIN number 0910–AG43, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–

Regulatory Information Number (RIN 0910–AG43) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov*, insert the docket number found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

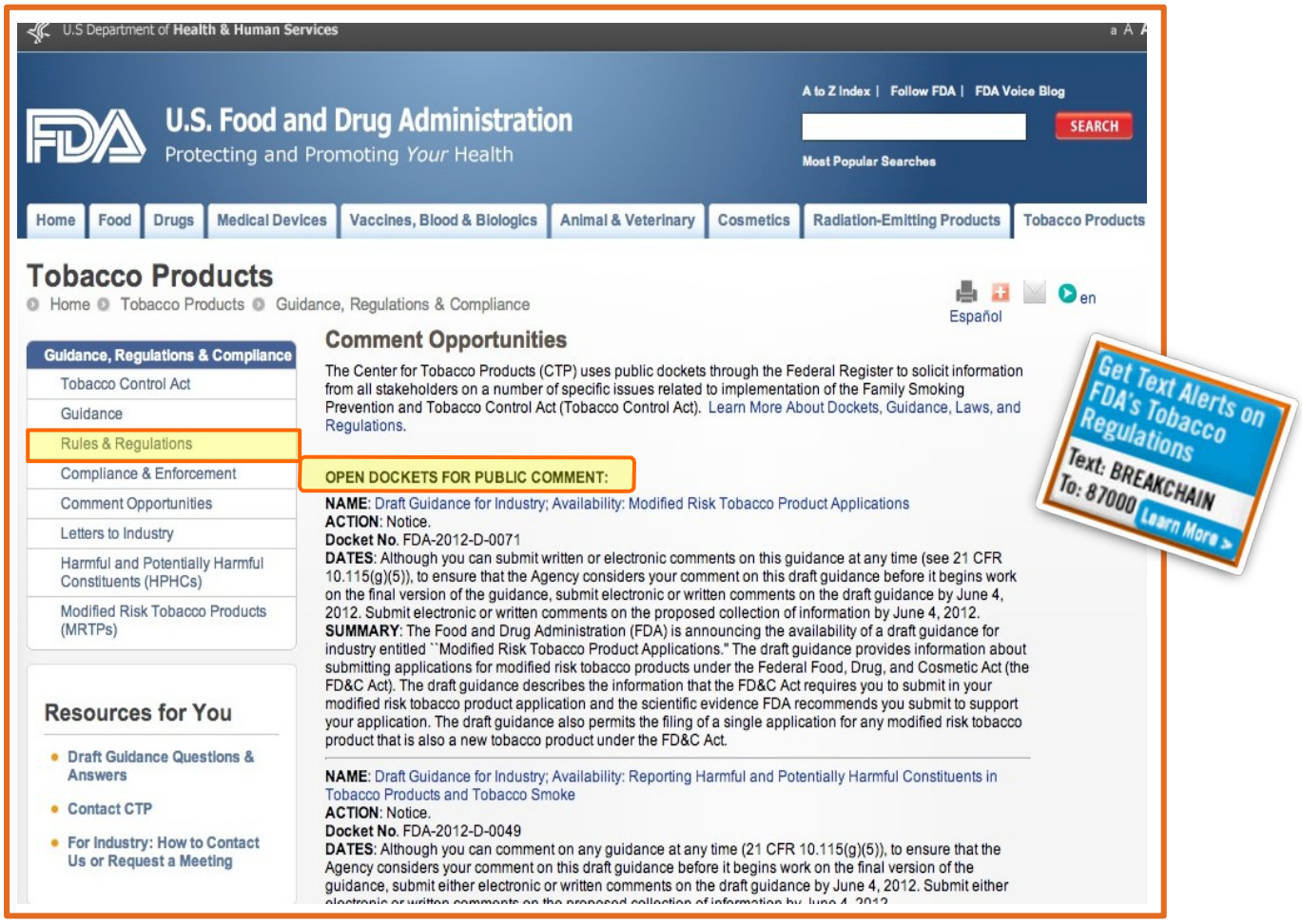
FOR FURTHER INFORMATION CONTACT: Beth Buckler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373, *beth.buckler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Tobacco Control Act, enacted on June 22, 2009, amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and provides FDA with the authority to regulate tobacco products (Pub. L. 111–31, 123 Stat. 1776). Among other things, the Tobacco Control Act requires FDA to issue regulations, by October 1, 2011, regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer (*i.e.*, a non-face-to-face or remote sale) in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including requirements for age verification (section 906(d)(4)(A)(i) of the FD&C Act (21 U.S.C. 387f(d)(4)(A)(i))). The Tobacco Control Act also requires FDA to issue regulations, by April 1, 2012, to address the promotion and marketing of tobacco products that are sold or distributed through a non-face-to-face exchange in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of such products (section 906(d)(4)(A)(ii)). Furthermore, section 906(d)(1) of the FD&C Act provides that

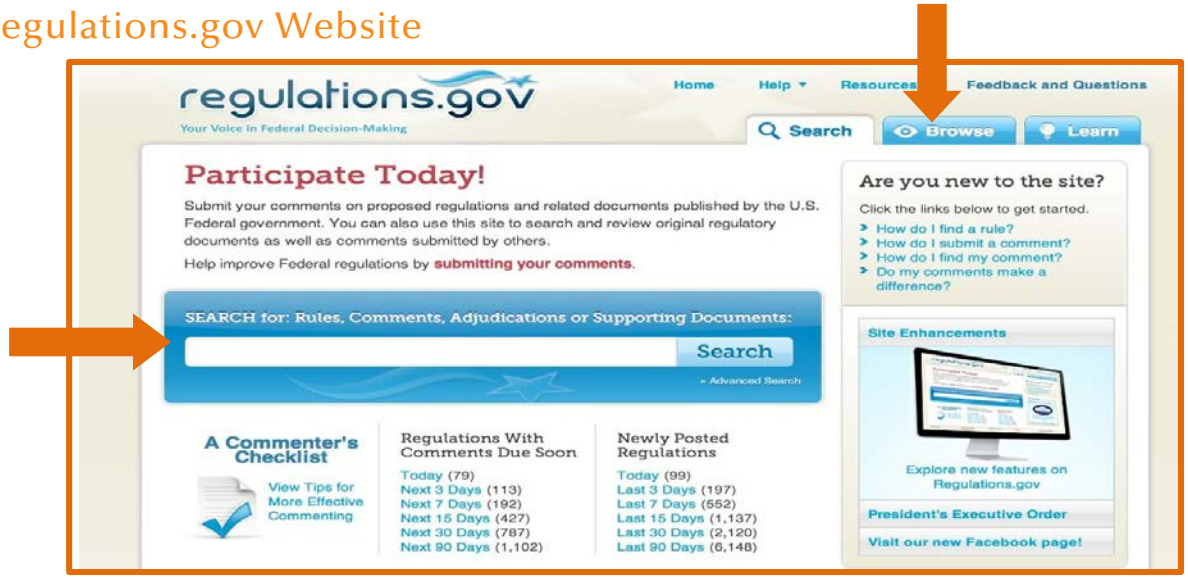
Regulating Agency Website



Many **agencies** post their proposed rules on their website. For example, the FDA's website has a "Tobacco Products" section identifying dockets currently open for public comment.

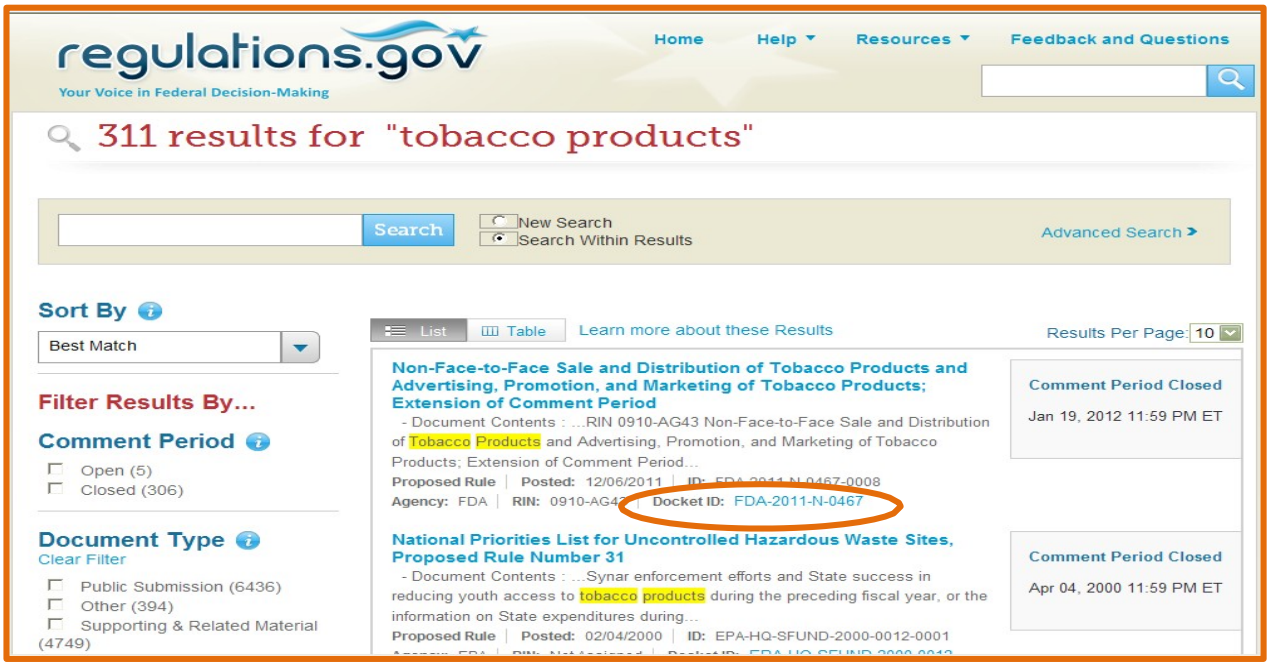
You may also register for FDA email or text general updates regarding tobacco products, including relevant rules.[14]

Regulations.gov Website



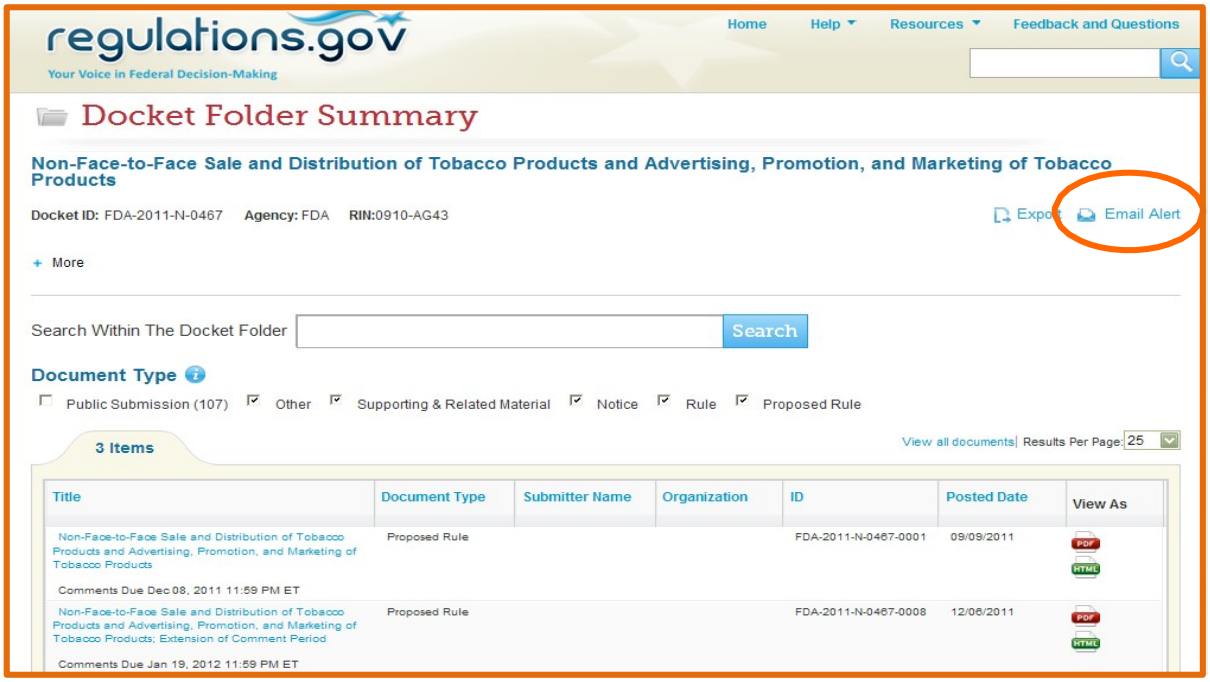
Regulations.gov lists all open matters or "dockets" for all federal agencies. **Search** by title, docket number, agency or keywords, such as "secondhand smoke" or "tobacco products" to find related rules open for comment.

Or, **browse** the site by featured regulations and subject. Tobacco control regulations may fall under "Food Safety, Health, and Pharmaceutical."



You may **narrow your search** using the filter, located on the left side of the screen. For example, you may opt to view only **open proposed rules**.

To view or register for **Regulations.gov** alerts about a specific proposed rule, locate the rule on the website, then navigate to the "Docket Folder Summary" by clicking the **Docket ID hyperlink**.



The Docket Folder Summary page posts links to communications about the rule, such as comment period extensions and recent additions or redactions as well as third party comments on the proposal. (Check back - your comment may ultimately be filed and placed in this docket!)

The Docket Folder Summary page also links to the **"Email Alert"** registration page.

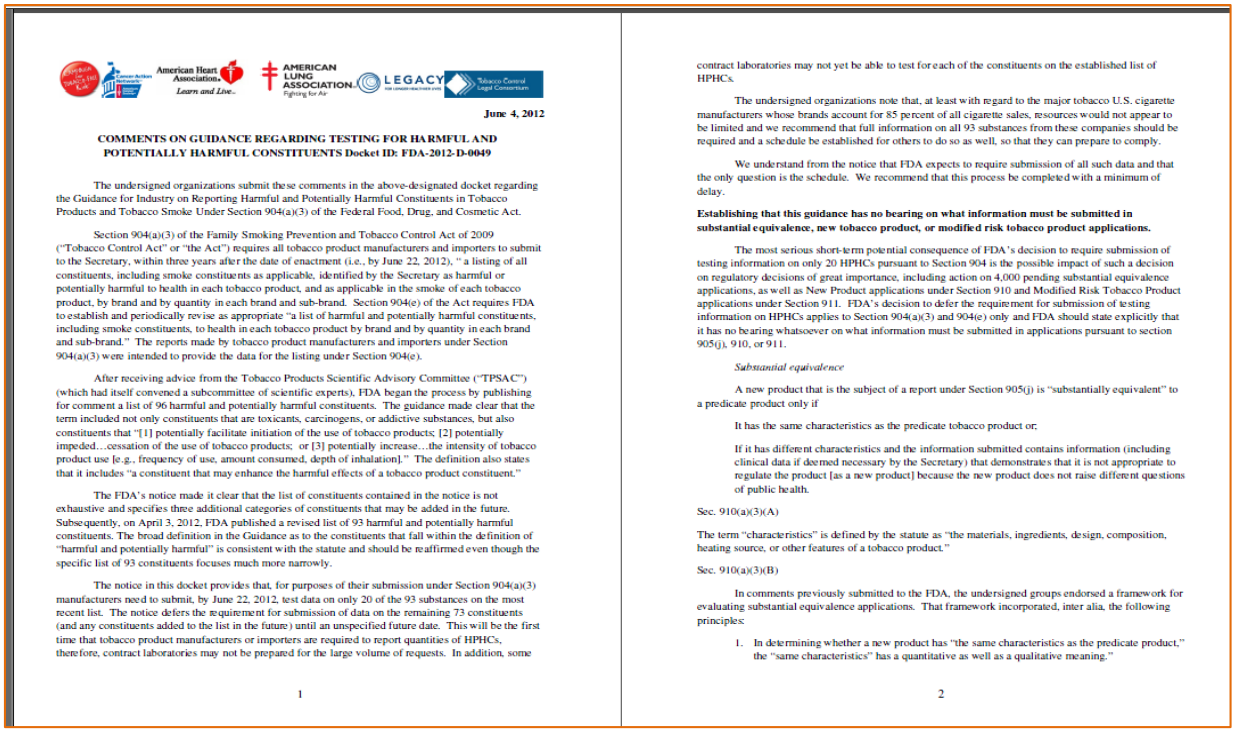
Step Two – Drafting a Comment

Who may comment on proposed rules?

Everyone is invited to submit a comment. Private individuals, subject matter experts, affected persons, communities or businesses, non-profits and health departments are just some examples of parties whose participation in the rulemaking process help strengthen an agency rule. Tobacco companies make it a priority to ensure the industry's perspective is well represented. They typically submit numerous lengthy comments, citing industry-funded research and data. It is crucial to balance that perspective and ensure the agency receives the opinions and perspectives of the public health community.

What should comments look like?

- ✓ Provide a clear statement of whether you support or oppose the proposed rule or guidance. Determine whether the agency is seeking general comments or guidance on a specific question and accordingly tailor your remarks. It is important to make your comment relevant or the agency will not be required to address your issue.[15]
- ✓ Explain why you support or disagree with the existing proposal, and include rationale for your suggested changes.
- ✓ Detail the information and/or professional or personal experiences that support your opinion.
  - o State your opinion as specifically as possible, provide as much support for your opinion as you can, and explain - preferably with real world examples - your concerns and how your suggestions benefit the public.[16]
  - o When applicable, *include a copy of articles or other references*.
- ✓ Be sure to identify the proposed regulation or guidance on which you are commenting by including the docket number, the subject heading, or the citation to the Federal Register.[17]



American Heart Association. Learn and Live. AMERICAN LUNG ASSOCIATION. Fighting for Air LEGACY Tobacco Control Legal Consortium

June 4, 2012

COMMENTS ON GUIDANCE REGARDING TESTING FOR HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS Docket ID: FDA-2012-D-0049

The undersigned organizations submit these comments in the above-designated docket regarding the Guidance for Industry on Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act.

Section 904(a)(3) of the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act" or "the Act") requires all tobacco product manufacturers and importers to submit to the Secretary, within three years after the date of enactment (i.e., by June 22, 2012), " a listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and sub-brand. Section 904(e) of the Act requires FDA to establish and periodically revise as appropriate "a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and sub-brand." The reports made by tobacco product manufacturers and importers under Section 904(a)(3) were intended to provide the data for the listing under Section 904(e).

After receiving advice from the Tobacco Products Scientific Advisory Committee ("TPSAC") (which had itself convened a subcommittee of scientific experts), FDA began the process by publishing for comment a list of 96 harmful and potentially harmful constituents. The guidance made clear that the term included not only constituents that are toxicants, carcinogens, or addictive substances, but also constituents that "[1] potentially facilitate initiation of the use of tobacco products; [2] potentially impeded…cessation of the use of tobacco products; or [3] potentially increase…the intensity of tobacco product use [e.g., frequency of use, amount consumed, depth of inhalation]." The definition also states that it includes "a constituent that may enhance the harmful effects of a tobacco product constituent."

The FDA's notice made it clear that the list of constituents contained in the notice is not exhaustive and specifies three additional categories of constituents that may be added in the future. Subsequently, on April 3, 2012, FDA published a revised list of 93 harmful and potentially harmful constituents. The broad definition in the Guidance as to the constituents that fall within the definition of "harmful and potentially harmful" is consistent with the statute and should be reaffirmed even though the specific list of 93 constituents focuses much more narrowly.

The notice in this docket provides that, for purposes of their submission under Section 904(a)(3) manufacturers need to submit, by June 22, 2012, test data on only 20 of the 93 substances on the most recent list. The notice defers the requirement for submission of data on the remaining 73 constituents (and any constituents added to the list in the future) until an unspecified future date. This will be the first time that tobacco product manufacturers or importers are required to report quantities of HPHCs, therefore, contract laboratories may not be prepared for the large volume of requests. In addition, some

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contract laboratories may not yet be able to test for each of the constituents on the established list of HPHCs.

The undersigned organizations note that, at least with regard to the major tobacco U.S. cigarette manufacturers whose brands account for 85 percent of all cigarette sales, resources would not appear to be limited and we recommend that full information on all 93 substances from these companies should be required and a schedule be established for others to do so as well, so that they can prepare to comply.

We understand from the notice that FDA expects to require submission of all such data and that the only question is the schedule. We recommend that this process be completed with a minimum of delay.

Establishing that this guidance has no bearing on what information must be submitted in substantial equivalence, new tobacco product, or modified risk tobacco product applications.

The most serious short-term potential consequence of FDA's decision to require submission of testing information on only 20 HPHCs pursuant to Section 904 is the possible impact of such a decision on regulatory decisions of great importance, including action on 4,000 pending substantial equivalence applications, as well as New Product applications under Section 910 and Modified Risk Tobacco Product applications under Section 911. FDA's decision to defer the requirement for submission of testing information on HPHCs applies to Section 904(a)(3) and 904(e) only and FDA should state explicitly that it has no bearing whatsoever on what information must be submitted in applications pursuant to section 905(j), 910, or 911.

Substantial equivalence

A new product that is the subject of a report under Section 905(j) is "substantially equivalent" to a predicate product only if

It has the same characteristics as the predicate tobacco product or;

If it has different characteristics and the information submitted contains information (including clinical data if deemed necessary by the Secretary) that demonstrates that it is not appropriate to regulate the product [as a new product] because the new product does not raise different questions of public health.

Sec. 910(a)(3)(A)

The term "characteristics" is defined by the statute as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product."

Sec. 910(a)(3)(B)

In comments previously submitted to the FDA, the undersigned groups endorsed a framework for evaluating substantial equivalence applications. That framework incorporated, inter alia, the following principles:

1. In determining whether a new product has "the same characteristics as the predicate product," the "same characteristics" has a quantitative as well as a qualitative meaning."

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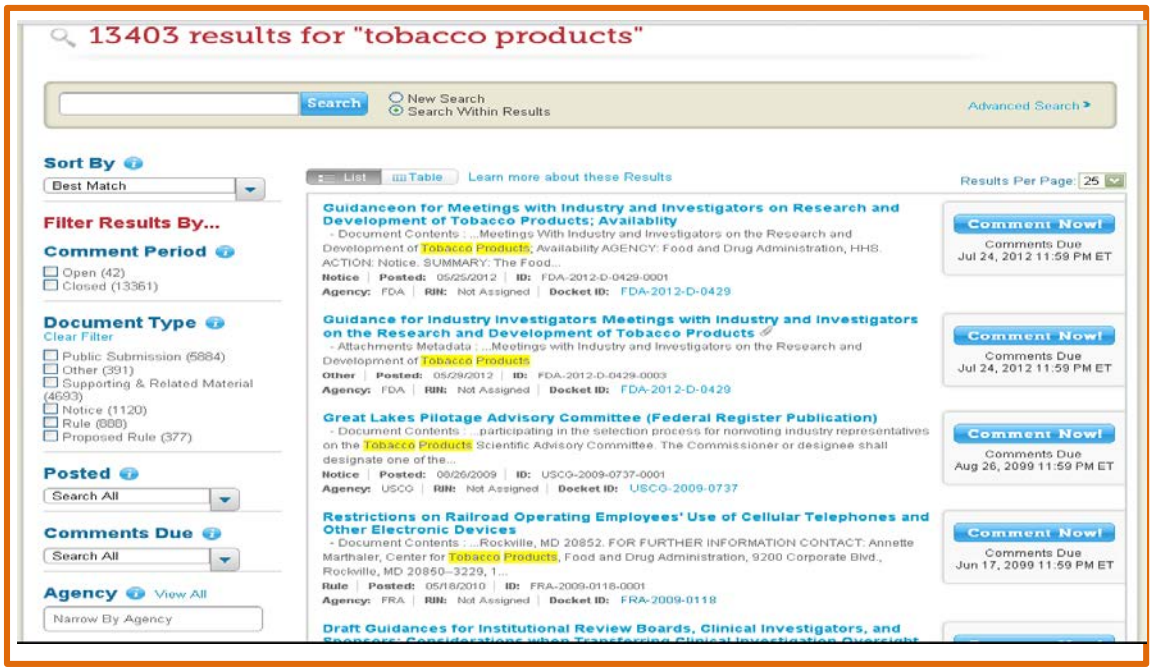
Step Three – Submitting a Comment

How may I comment on proposed rules?

a) Submit a comment through the interweb
b) Submit a comment by facsimile or US Post

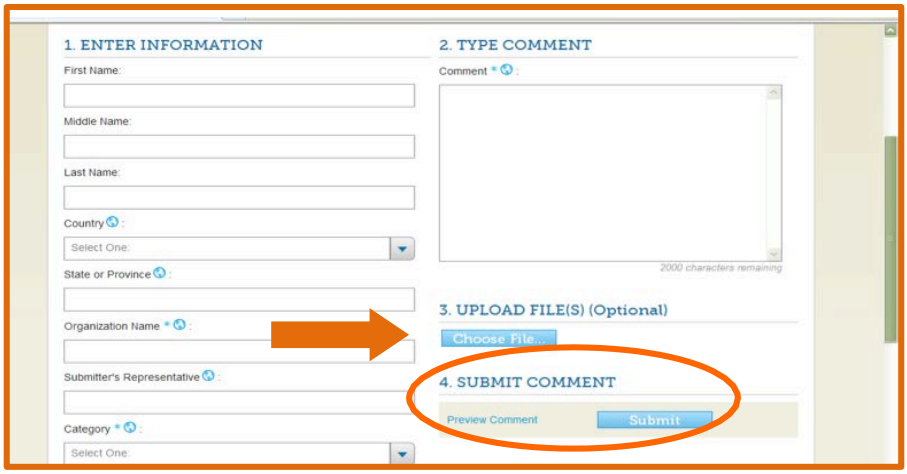
Submitting a comment through the interweb



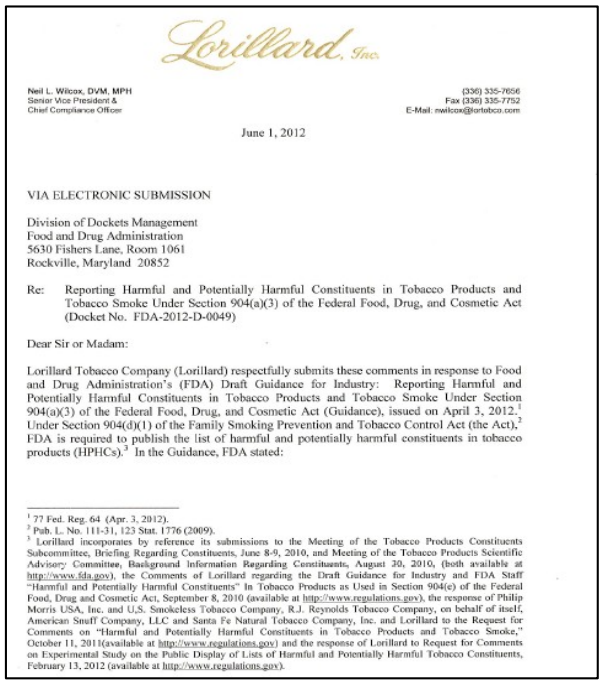
Submit comments via the internet using **Regulations.gov**. Upon finding a proposed regulation of interest, click its title to review, or click **"Comment Now!"** to submit your comment.

Selecting "Comment Now!" brings you to the comment submission page. Here, you may **type** your comments on the screen or **upload a file** containing your comment.

If you enter your comments directly onto the webpage, you will still have the *option to preview and edit* it prior to Submission; click **"Preview Comment"** or **"Submit."**



Examples of comments submitted as a file attachment through regulations.gov.



Lorillard, Inc.

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June 1, 2012

VIA ELECTRONIC SUBMISSION

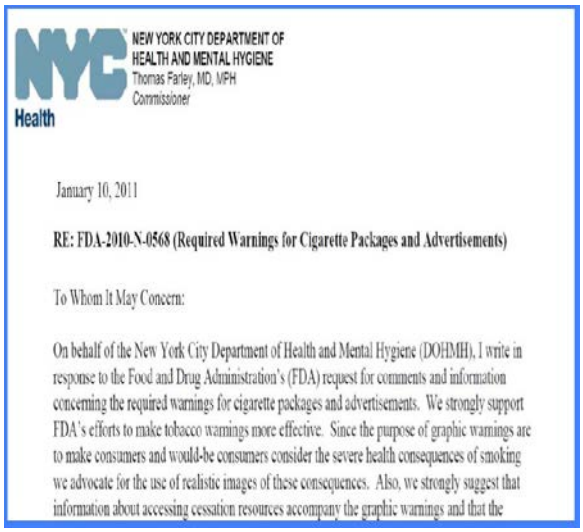
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act (Docket No. FDA-2012-D-0049)

Dear Sir or Madam:

Lorillard Tobacco Company (Lorillard) respectfully submits these comments in response to Food and Drug Administration's (FDA) Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act (Guidance), issued on April 3, 2012.[1] Under Section 904(d)(1) of the Family Smoking Prevention and Tobacco Control Act (the Act),[2] FDA is required to publish the list of harmful and potentially harmful constituents in tobacco products (HPHCs).[3] In the Guidance, FDA stated:

[1] 77 Fed. Reg. 64 (Apr. 3, 2012).
[2] Pub. L. No. 111-31, 123 Stat. 1776 (2009).
[3] Lorillard incorporates by reference its submissions to the Meeting of the Tobacco Products Constituents Subcommittee, Briefing Regarding Constituents, June 8-9, 2010, and Meeting of the Tobacco Products Scientific Advisory Committee, Background Information Regarding Constituents, August 30, 2010, (both available at http://www.fda.gov), the Comments of Lorillard regarding the Draft Guidance for Industry and FDA Staff "Harmful and Potentially Harmful Constituents" In Tobacco Products as Used in Section 904(e) of the Federal Food, Drug and Cosmetic Act, September 8, 2010 (available at http://www.regulations.gov), the response of Philip Morris USA, Inc. and U.S. Smokeless Tobacco Company, R.J. Reynolds Tobacco Company, on behalf of itself, American Snuff Company, LLC and Santa Fe Natural Tobacco Company, Inc. and Lorillard to the Request for Comments on "Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke," October 11, 2011(available at http://www.regulations.gov) and the response of Lorillard to Request for Comments on Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents, February 13, 2012 (available at http://www.regulations.gov).



NYC Health

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Thomas Farley, MD, MPH
Commissioner

January 10, 2011

RE: FDA-2010-N-0568 (Required Warnings for Cigarette Packages and Advertisements)

To Whom It May Concern:

On behalf of the New York City Department of Health and Mental Hygiene (DOHMH), I write in response to the Food and Drug Administration's (FDA) request for comments and information concerning the required warnings for cigarette packages and advertisements. We strongly support FDA's efforts to make tobacco warnings more effective. Since the purpose of graphic warnings are to make consumers and would-be consumers consider the severe health consequences of smoking we advocate for the use of realistic images of these consequences. Also, we strongly suggest that information about accessing cessation resources accompany the graphic warnings and that the

Example of comment typed directly onto regulations.gov webpage.

regulations.gov
Your Voice in Federal Decision-Making

Home Help Resources Feedback and Questions

Document Details

Lynn R Antil - Comment

Document ID: FDA-2012-D-0049-0009

Document Type: Public Submission

This is comment on Notice: Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act; Availability

Docket ID: FDA-2012-D-0049

View Document:

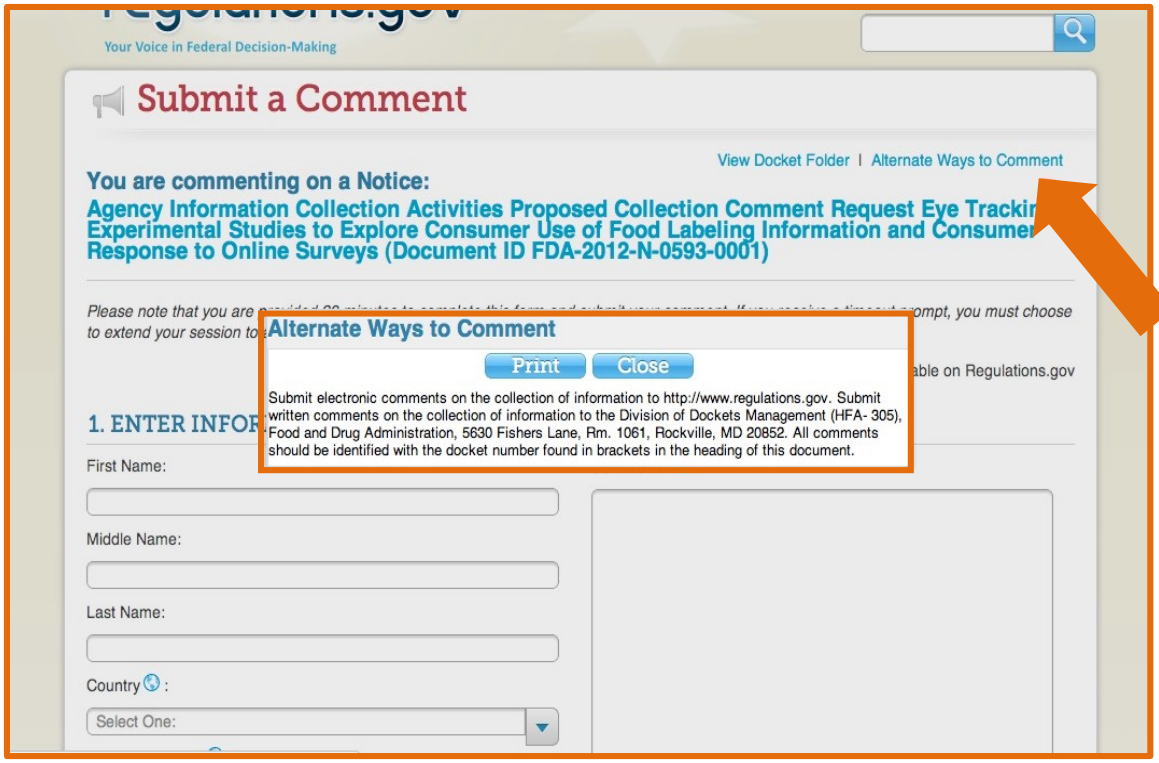
+ More

Tobacco manufacturers should be required to let the consumer know exactly what is in the tobacco products. I would like to see a label (similar to a nutrition label on food) that lists the known carcinigens/toxic chemicals in the tobacco product, irregardless of the type of tobacco (cigarettes, cigars, smokeless tobacco, etc.). When I tell current tobacco users about some of the ingredients of a cigarette, they are often outraged and ask why the government would allow tobacco products to be sold to consumers. By requiring tobacco manufacturer's to disclose what is in their products, consumers can make a more informed decision about what they put into their bodies.

Home About Us Resources Help Connect With

Submitting by fax or US Post

Comments may be faxed or mailed to the agency using the address and contact person stated in the Federal Register. The Federal Register will also include the deadline for submitting comments on proposed regulations. Be sure any submission includes the rule title and docket number.



Some agencies also provide a U.S. Postal address on regulations.gov. If so, the comment submission page will offer **"Alternate Ways to Comment,"** which displays the U.S. Postal address to which comments may be sent.[18]

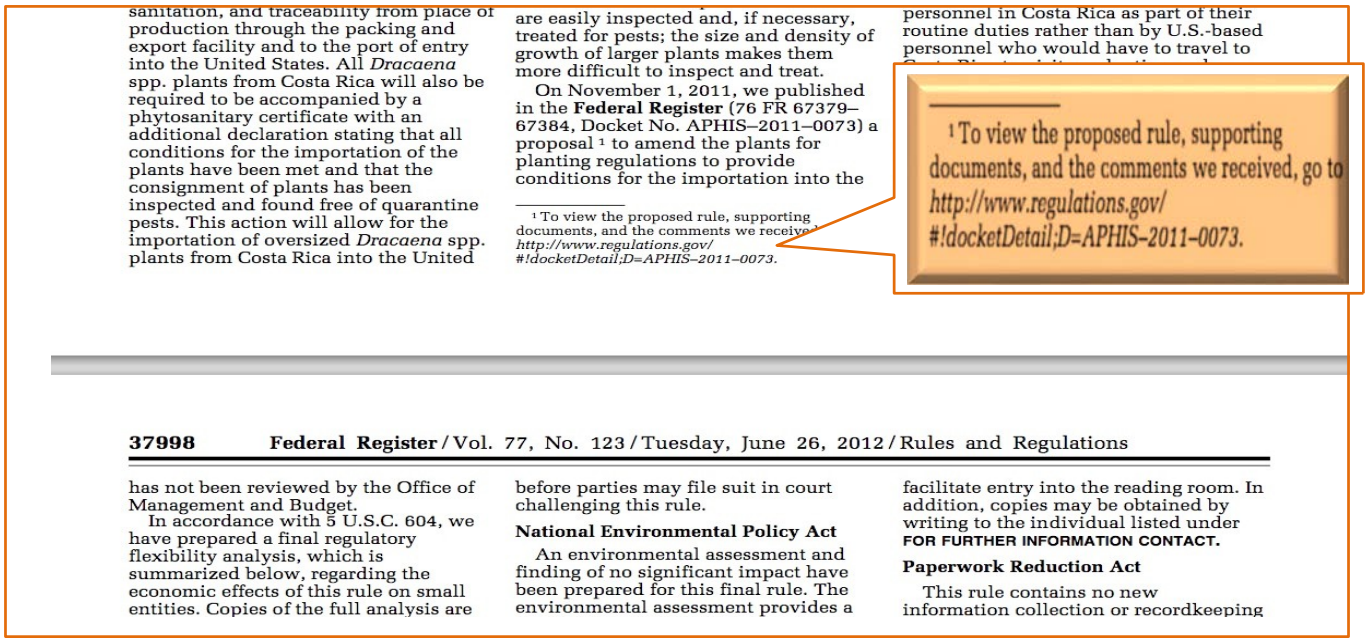
Step Four – After Comment Submission

What to expect after submitting a comment.

- If you submit your comment electronically through regulations.gov, upon submission you will receive a confirmation page with a "Comment Tracking Number." This unique number is the easiest way to recall your comment in the future. After the agency has processed your comment it will be posted to the regulations.gov website.
- If you submit a comment through U.S. Mail, consider using a delivery service, such as certified mail, signature confirmation or delivery confirmation. Do not expect the agency to confirm receipt of a submission. However, your comment may also be posted on regulations.gov, along with comments submitted directly through the internet.
- Allow time for processing; your comment may not appear in the electronic docket for several weeks, regardless of submission method.
- An agency is not obligated to respond individually to each individual comment; however, the published record must acknowledge all received submissions.

How can I be sure an agency has read my comment?

- The Final Rule must be published in the Federal Register and must include:
  - Summaries of all relevant comments the agency received during the notice and comment period; and
  - An explanation of the agency's reasoning for making or not making changes consistent with the comments they received.[19]
- These comments and the agency response to them are compiled and available to the public; visit **regulations.gov** or the website identified in the publication of the final rule.
- Review the comment summaries and note the agency response. The concept of your comment should be reflected, even if it is worded differently from your submission. Record must acknowledge all received submissions.



sanitation, and traceability from place of production through the packing and export facility and to the port of entry into the United States. All *Dracaena* spp. plants from Costa Rica will also be required to be accompanied by a phytosanitary certificate with an additional declaration stating that all conditions for the importation of the plants have been met and that the consignment of plants has been inspected and found free of quarantine pests. This action will allow for the importation of oversized *Dracaena* spp. plants from Costa Rica into the United

are easily inspected and, if necessary, treated for pests; the size and density of growth of larger plants makes them more difficult to inspect and treat.

On November 1, 2011, we published in the **Federal Register** (76 FR 67379–67384, Docket No. APHIS–2011–0073) a proposal [1] to amend the plants for planting regulations to provide conditions for the importation into the

[1] To view the proposed rule, supporting documents, and the comments we receive, go to *http://www.regulations.gov/#!docketDetail;D=APHIS–2011–0073.*

personnel in Costa Rica as part of their routine duties rather than by U.S.-based personnel who would have to travel to

[1] To view the proposed rule, supporting documents, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS–2011–0073.*

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has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have prepared a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are

before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a

facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping

Resources

Federal Register	https://www.federalregister.gov/
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Food & Drug Administration Information on Notice & Comment	http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm
Food & Drug Administration Comment Online	www.regulations.gov (enter “Food and Drug Administration” or notice number in the search box)
Food & Drug Administration Subscribe to Tobacco Products Regulations Listserv	https://public.govdelivery.com/accounts/USFDA/subscriber/new?topic_id=USFDA_131
New York State Department of Health Tobacco Control Website	http://www.health.ny.gov/prevention/tobacco_control/
New York State Department of Health Mailing Address	New York State Department of Health Corning Tower Empire State Plaza Albany, NY 12237
New York State Department of Health ATUPA Guide	http://www.health.ny.gov/prevention/tobacco_control/tobguide.htm

Citations

[1] *About the Federal Register*, NATIONAL ARCHIVES, http://www.archives.gov/federal-register/the-federal-register/about.html (last visited June 14, 2012).

[2] 5 U.S.C.A. § 553(c) (West 2012).

[3] GOVERNMENT PRINTING OFFICE, KEEPING AMERICA INFORMED 81-85 (2010), *available at* http://www.gpo.gov/fdsys/pkg/GPO-KEEPINGAMERICAINFORMED/pdf/GPO-KEEPINGAMERICAINFORMED.pdf; *Comment on Regulations*, UNITED STATES FOOD AND DRUG ADMINISTRATION (Feb. 7, 2008), http://www.fda.gov/AboutFDA/ContactFDA/CommentonRegulations/default.htm.

[4] 5 U.S.C.A. § 553.

[5] *Id.* § 553(d). *See also, Getting Your Voice Heard: Commenting on Federal Regulations*, PUBLIC HEALTH LAW & POLICY (November 2010), http://www.phlpnet.org/sites/phlpnet.org/files/FDA_Law_Notes_3_Commenting_on_Fed_Reg_FINAL_20101117.pdf; VANESSA K. BURROWS & TODD GARVEY, CONG. RESEARCH SERV., R41546, A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW (2011), *available at* http://www.wise-intern.org/orientation/documents/CRSrulemakingCB.pdf.

[6] 5 U.S.C.A. § 557(c)(3).

[7] 2 U.S.C. § 1602(8)(B)(x) (2006).

[8] N.Y. LEGIS. LAW § 1-c (c)(E) (McKinney) (2011).

[9] *Find a Regulation*, REGULATIONS.GOV, http://www.regulations.gov/#!help (last visited June 26, 2012).

[10] *Id.*

[11] *Public Comments Make a Difference*, REGULATIONS.GOV, http://www.regulations.gov/docs/FactSheet_Public_Comments_Make_a_Difference.pdf (last visited June 26, 2012).

[12] 5 U.S.C.A. § 552 (West 2012).

[13] 5 U.S.C. § 706(2) (2012).

[14] To sign up for docket updates through regulations.gov, go to the docket folder, click “sign up for E-mail alerts” link and enter your e-mail address along with the frequency of updates you would like to receive. *Frequently Asked Questions*, REGULATIONS.GOV, http://www.regulations.gov/#!faqs;qid=6-2 (last visited June 14, 2012).

[15] *About the Federal Register*, *supra* note 1.

[16] *Rulemaking Process at the FCC*, FEDERAL COMMUNICATIONS COMMISSION, http://www.fcc.gov/encyclopedia/rulemaking-process-fcc#q10 (last visited June 8, 2012).

[17] *Frequently Asked Questions*, REGULATIONS.GOV, *supra* note 14.

[18] To find out if an agency accepts comment by mail, click the “Alternate Ways to Comment Link” on the online comment page through regulations.gov (displayed on page 5). *Frequently Asked Questions*, REGULATIONS.GOV, *supra* note 14.

[19] 5 U.S.C.A. § 553 (West 2012).

Public Health and Tobacco Policy Center

Providing legal expertise to support policies benefiting the public health.

The **Public Health and Tobacco Policy Center** is a legal research Center within the Public Health Advocacy Institute. Our shared goal is to support and enhance a commitment to public health in individuals and institutes who shape public policy through law. We are committed to research in public health law, public health policy development; to legal technical assistance; and to collaborative work at the intersection of law and public health. Our current areas of work include tobacco control and chronic disease prevention. We are housed at the Northeastern University School of Law in Boston, Massachusetts.

What We Do

Research & Information Services

- analyze and contextualize the legal landscape and scientific evidence base for emerging issues in tobacco control and other public health policy areas
- develop model policies for implementation at the organizational, municipal, or state level
- compile and analyze policy initiatives and litigation related to impactful health policy

Legal Technical Assistance

- assist local governments with identifying effective, feasible policy responses addressing public health concerns
- draft tailored policies to address municipalities' unique concerns
- assist local governments with policy enactment and implementation

Education & Outreach

- conduct in-person and online trainings that convey the legal landscape for promising policy interventions, their potential impact on a public health problem, best practices, common obstacles, and lessons learned
- facilitate strategic planning for public health agencies and other regulators
- maintain website featuring technical reports, model policies, fact sheets, toolkits, story maps, summaries of tobacco control laws
- impact development of national and federal tobacco control laws and regulations, including through collaboration with partners and *amicus curiae* briefs

Find Us Online

www.tobaccopolicycenter.org

The Policy Center's website provides information about local policy interventions to improve population health. We highlight factors driving tobacco use and policy solutions addressing these factors; authority and rationale for implementing local tobacco controls, and relevant federal, state, and local policies in effect in New York State. We provide contextualized summaries of recent court cases affecting tobacco product and sales regulation, newsletter summaries of relevant current issues, and more. The website provides convenient access to the Policy Center's technical reports, toolkits, model policies, fact sheets, presentations, and story maps.

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Requests for Legal Technical Assistance

The Public Health and Tobacco Policy Center provides legal background and policy guidance for research, development, and implementation of tobacco control strategies and policies. We do not represent clients or provide legal advice. The Policy Center is a resource for the New York tobacco control community. Individuals from state-funded coalitions and local governments may contact us with tobacco-related legal or policy issues at **tobacco@tobaccopolicycenter.org**.

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