

The Food Safety Modernization Act

How Do I Comment on the Proposed Rules?

The Food and Drug Administration will accept comments submitted online or through the mail. Follow these instructions to submit your own comments to FDA!

Comments are due November 15, 2013!

Comment by Mail:

If you are submitting a written comment by mail, you can type or hand-write your comments and mail them to this address:

Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

All submissions received must include the following:

- Your Name
- Your Organization (if any)
- The appropriate docket number:
 - o For the Preventive Controls Rule: FDA-2011-N-0920 and RIN 0910-AG36
 - o For the Produce Rule: FDA-2011-N-0921, and RIN 0910-AG35

If you want to comment on both rules, you can mail them together but must label them separately.

Note: FDA states that all comments received may be posted without change to www.regulations.gov, including any personal information provided.

Comment Online:

1. Do your homework! Check out NSAC's FSMA resources online and peruse the rules yourself. You can access the rules and our analysis here, including tips on what your comment might include and good questions to ask: http://www.sustainableagriculture.net/fsma

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- 2. Click on the appropriate rule page in *Regulations.gov* either the <u>Produce Rule¹</u> (FDA-2011-N-0921) or the <u>Preventive Controls Rule.²</u> (FDA-2011-N-0920) You can comment on both rules, but you must comment separately. If you're not certain which issues apply to which rule, refer to our explanation of the rules and issues pages. Some issues affect both rules this means you'll have to submit a separate comment on each form for each rule if you want to comment on that issue.
- 3. Click on the "Comment Now!" button on the right-hand side of the page:

Comment Now!

- 4. Double-check that you are commenting on the correct rule on the next page, if you are commenting on the Produce Rule, it will say: <u>Standards for the Growing</u>, <u>Harvesting</u>, <u>Packing</u>, <u>and Holding of Produce for Human Consumption</u>; <u>Extension of Comment Periods</u>. If you are commenting on the Preventive Controls Rule, it will say: <u>Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food</u>; <u>Extension of Comment Periods</u>.
- 5. Enter your comments and personal and business information under Section 1,



Your Information

which is labeled like this:

- 6. First up is the comment box where your FSMA comments will go. You can type them right into the box, paste them in from another document, or upload a separate file. Whatever you do, we strongly recommend you pre-draft and prepare your thoughts ahead of time using a word processor like Word or good old-fashioned pen and paper! Note that there is a 5000-character limit for the box this is about one and a half pages of single-spaced typed text or around 700-750 words. If you think you have more to say, you should UPLOAD a separate document with your longer comments instead and type "See attached file" in the box.
- 7. Enter your first and last name (or opt to remain anonymous).
- 8. (Optional) Click the box that says "I want to provide my contact information" and enter your ZIP code and email address. It's a good idea to provide your contact information so that FDA can follow up with you if they have questions, and your contact information will not be made public.
- 9. (Optional) If you are entering a comment on behalf of someone else, check the "I am submitting on behalf of a third party" box.

¹ http://bit.ly/fsma-pr

² http://bit.ly/fsma-pcr



- 10. Select which category you fall into. There are many options, including "Individual Consumer" and "Food Industry" ("Food Industry" is what you should choose if you are a farmer or food processor).
- 11. Click the "Continue" link to preview your comments and ensure everything is

Your Preview

accurate on the next screen:

- 12. Note: you cannot edit your comment once you submit it but if you see a mistake, you can click the "Edit" button at the bottom to go back and make changes.
- 13. Click "Submit Comment" to officially submit your comment to FDA.

Submit Comment

- You did it! FDA will read every comment submitted. They may not respond to each comment individually but they will address the substance of these public comments publicly once the comment period has closed.
- 14. A screen will appear with a confirmation number for your comment. Copy this down you can use it later to ensure your comment was received. Your comment may not appear on *Regulations.gov* right away!

A Few Final Tips:

- **Having trouble?** Check out the <u>official Regulations.gov help page</u>³ or contact the Regulations.gov help desk they have both email and phone options (Phone: 1-877-378-5457)
- **Make a mistake?** To make changes, submit another comment referring to your previous comment, correcting any errors and/or re-stating your position or opinion.
- **Want to submit additional comments?** You can submit more than one comment simply follow this process again!
- Remember to keep a separate copy of your comment just in case! This way if you have a problem submitting it or need to reference it later, you've got a copy.

³ http://www.regulations.gov/#!help