

An In-Depth Look at FDA's FSMA Technical Assistance Network

**American Spice Trade Association
October 11, 2017**



Sharmi Das, MHS
FDA - Center for Food Safety and Applied Nutrition



FDA FSMA Technical Assistance Network

- Launched FDA's FSMA Technical Assistance Network on September 9, 2015
- Provide technical assistance to industry, regulators, academia, and consumers regarding FSMA
- Address questions related to FSMA rules, programs, and implementation
- Collaborate with external technical resources, e.g. Alliances, Extension Specialists, Universities, International Partners

How to Contact Us?

• Meetings, Hearings, and Workshops

- Produce Safety Final Rule and Environmental Impact Statement
- Foreign Supplier Verification Programs (FSVP) Final Rule
- Accredited Third-Party Certification Final Rule
- Preventive Controls for Human Food Final Rule
- Preventive Controls for Food for Animals Final Rule
- All Activity by Date

Contact Us
Submit your FSMA questions either electronically or by mail to the Technical Assistance Network (TAN)

- www.fda.gov/FSMA
- Go to Contact Us and **How to Contact FDA on FSMA**
- FSMA TAN Popular Topics posted April 2017
- Inquiries may be submitted by mail, if internet is not available.

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En EspaÑol

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Food

Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA)

Food Safety Modernization Act (FSMA)

- The Law, Rules & Guidance
- Fact Sheets & Presentations
- Frequently Asked Questions on FSMA
- FDA Actions and Meetings
- FSMA Training
- FSMA Technical Assistance Network (TAN)**

FSMA Technical Assistance Network (TAN)

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Have a FSMA Question? Start Here.

The Technical Assistance Network staff has compiled answers to **common FSMA TAN questions**. In addition, the complete set of **frequently asked questions on FSMA** contains answers to questions on specific provisions of the rule.

Submit Your Question

Didn't find your question above? Please [submit your question](#) to TAN for assistance.

Mail Your Question

If you prefer to mail in your question, please send it to the address below:
Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Note: For Food Safety Preventive Controls Alliance (FSPCA) training and scientific/technical questions, please contact the FSPCA Technical Assistance Network using their web form at <http://www.it.edu/itsh/valliance>.

How the TAN Works

Page Last Updated
Note: If you need
Language Assistance
English

U.S. Food
10/2017



Inquiry Web Form

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

A to Z Index | Follow FDA | FDA Voice Blog

Search FDA

Food and Cosmetics Information Center (FCIC) Inquiry Form
(FDA form # 3907)

* = Required Information

I am a member of this category * --None--

Email *

Country * --None--

Zip Code *

Is your inquiry specific to the Food Safety Modernization Act requirements(FSMA) * Yes No

Inquiry (2500 character limit) *

y o y j 9 u

Enter the code above here *

The Food and Drug Administration's (FDA), Food and Cosmetics Information Center (FCIC) will respond to your web inquiry as soon as possible. However, response times may vary, due to public health priorities and the high volume of inquiries we receive. We strive to provide the public with accurate and current information, which at times requires extensive research. Please be assured that we will respond as soon as possible. Thank you for your patience and for contacting FDA's FCIC.

Submit

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

A to Z Index | Follow FDA | FDA Voice Blog

Search FDA

Food and Cosmetics Information Center (FCIC) Inquiry Form
(FDA form # 3907)

* = Required Information

I am a member of this category * --None--

Email * Academia

Country * Consumer

Zip Code * Media

Is your inquiry specific to the Food Safety Modernization Act requirements(FSMA) * Yes No

Inquiry (2500 character limit) *

y o y j 9 u

Enter the code above here *

The Food and Drug Administration's (FDA), Food and Cosmetics Information Center (FCIC) will respond to your web inquiry as soon as possible. However, response times may vary, due to public health priorities and the high volume of inquiries we receive. We strive to provide the public with accurate and current information, which at times requires extensive research. Please be assured that we will respond as soon as possible. Thank you for your patience and for contacting FDA's FCIC.

Submit

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

A to Z Index | Follow FDA | FDA Voice Blog

Search FDA

Food and Cosmetics Information Center (FCIC) Inquiry Form
(FDA form # 3907)

* = Required Information

I am a member of this category * --None--

Email *

Country * --None--

Zip Code *

Is your inquiry specific to the Food Safety Modernization Act requirements(FSMA) * Yes No

FSMA Topics * --None--

Inquiry (2500 character limit) *

y o y j 9 u

Enter the code above here *

The Food and Drug Administration's (FDA), Food and Cosmetics Information Center (FCIC) will respond to your web inquiry as soon as possible. However, response times may vary, due to public health priorities and the high volume of inquiries we receive. We strive to provide the public with accurate and current information, which at times requires extensive research. Please be assured that we will respond as soon as possible. Thank you for your patience and for contacting FDA's FCIC.

Submit

Web Form Auto Response



The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has received your inquiry. Your inquiry has been assigned case number 00137603. Please retain this case number and reference it in future correspondence regarding this inquiry.

We will respond to your inquiry as soon as possible. However, response times may vary, due to public health priorities and the high volume of inquiries we receive.

We strive to provide the public with accurate and current information, which at times requires extensive research. Please be assured that we will respond as soon as possible.

Thank you for contacting FDA's FCIC/TAN.

FSMA
TECHNICAL ASSISTANCE
NETWORK





Inquiry Web Form Survey

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

A to Z Index | Follow FDA | FDA Voice Blog

Search FDA

Food and Cosmetics Information Center (FCIC) Inquiry Form
(FDA form # 3907)

Your participation/nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-responders), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.

U. S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Food and Cosmetics Information Center Inquiry Form Customer Satisfaction Survey

Please complete the following information regarding the use of the Food and Cosmetics Information Center (FCIC) Inquiry Form.
Thank you for taking the time to complete this evaluation.

1. How did you learn about this web form?

2. Were the web form instructions clear?

1 2 3 4 5

Not Clear Very Clear

3. What improvements can be made to this web form?

Thank you for your feedback!

Inquiry Web Form Survey

Survey Responses as of Sept. 15, 2017

Were Webform Survey Instructions Clear?

Survey Rating	Survey Count	% of Total
1	325	3%
2	443	4%
3	1,739	17%
4	2,840	27%
5	5,044	49%
Total		100%

How Public Learned of Web Form

Rank	Term
1	FDA Website
2	Google Search
3	Food Safety Training
3	PCQI Training

Areas To Improve

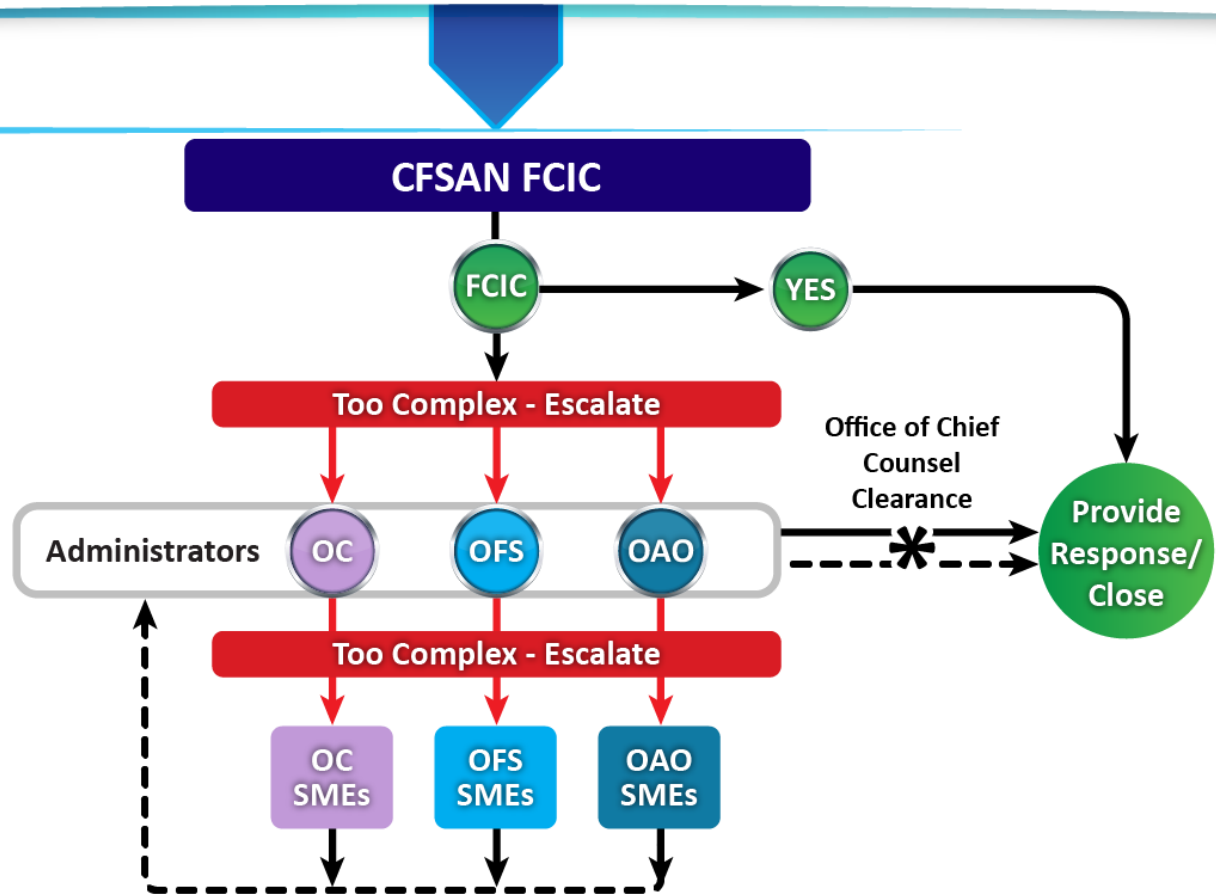
Rank	Term
1	Web Form Text Box
2	Live Chat with Specialist
3	Direct Contact Information for PO



TAN Process – CFSAN

Stakeholder Inquiries (Phone or Web Form)

TIER 2



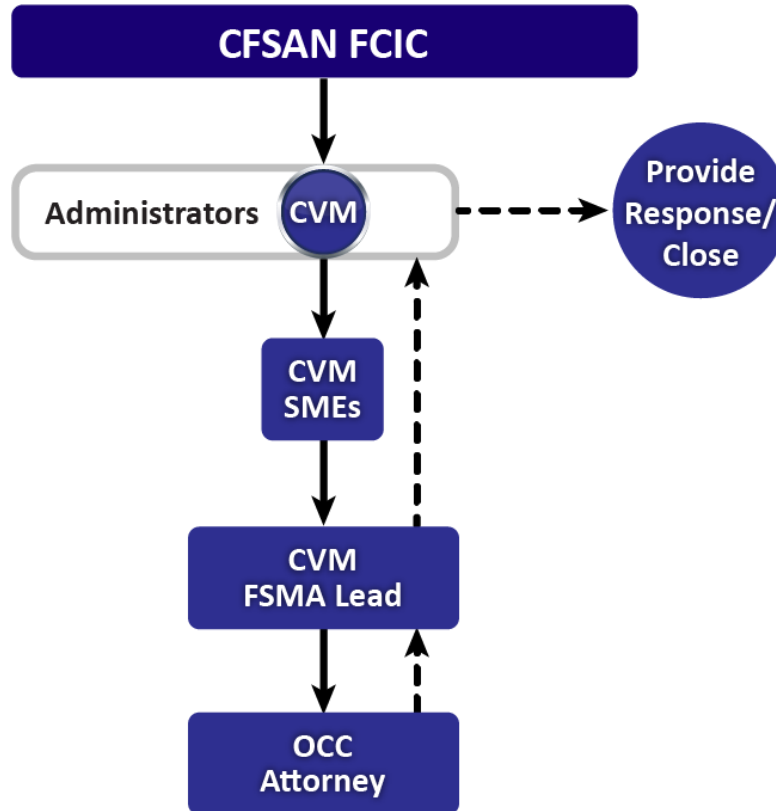
All SME responses go to the Administrator who will provide final response and close case.



TAN Process – CVM

Stakeholder Inquiries (Phone or Web Form)

TIER 2



FDA FSMA Technical Assistance Network

- The FSMA TAN received a total of 6,471 inquiries from September 9, 2015 through September 15, 2017. Of the FSMA inquiries received, 1,216 still remain open while 5,255 have been responded to and closed
- Median response time is 15 days
- Average response time is 44 days

FDA FSMA Technical Assistance Network

Sept 9, 2015 – Sept 15, 2017

Case Count by FSMA Topic

FSMA Topics	Inquiry Count
Preventive Controls-Human Food	2,279
Foreign Supplier Verification Program (FSVP)	1,298
Sanitary Transportation for Human and Animal Food	845
Produce Safety	664
Preventive Controls-Animal Food	456
Other	438
Accredited Third-Party Certification (3rd Party)	207
Food Facility Registration	177
Intentional Adulteration	74
Voluntary Qualified Importer Program (VQIP)	18
Lab Accreditation	15
Grand Total	6,471

Percentage of Total FSMA Cases by FSMA Topic

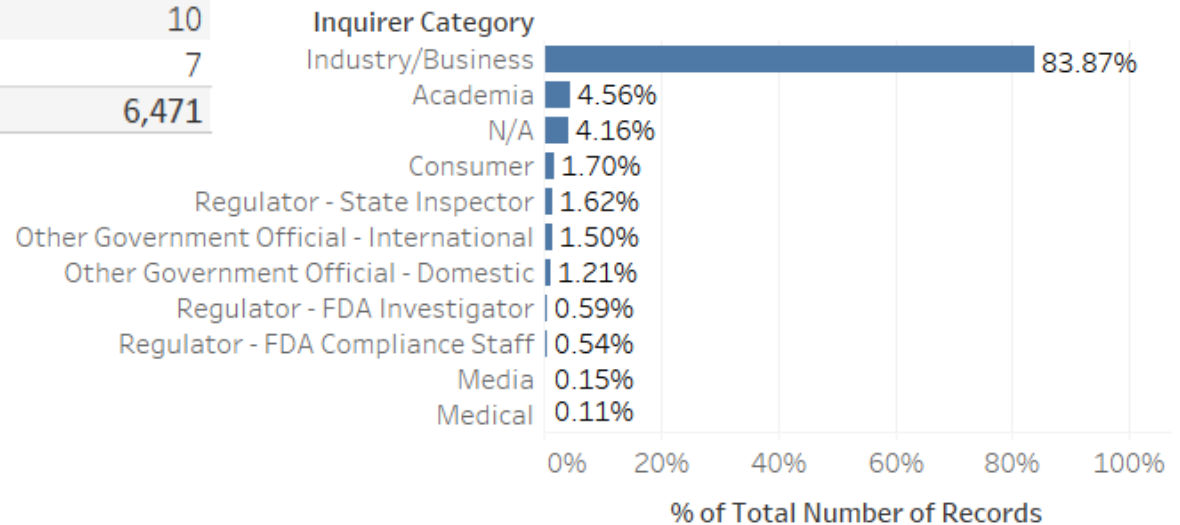
FSMA Topics	% of Total
Preventive Controls-Human Food	35.22%
Foreign Supplier Verification Program (FSVP)	20.06%
Sanitary Transportation for Human and Animal Food	13.06%
Produce Safety	10.26%
Preventive Controls-Animal Food	7.05%
Other	6.77%
Accredited Third-Party Certification (3rd Party)	3.20%
Food Facility Registration	2.74%
Intentional Adulteration	1.14%
Voluntary Qualified Importer Program (VQIP)	0.28%
Lab Accreditation	0.23%
Grand Total	100.00%

FDA FSMA Technical Assistance Network

Sept 9, 2015 – Sept 15, 2017

Inquirer Category	Inquiry Count
Industry/Business	5,427
Academia	295
N/A	269
Consumer	110
Regulator - State Inspector	105
Other Government Official - International	97
Other Government Official - Domestic	78
Regulator - FDA Investigator	38
Regulator - FDA Compliance Staff	35
Media	10
Medical	7
Grand Total	6,471

Percentage of Total FSMA Cases by Inquirer Category

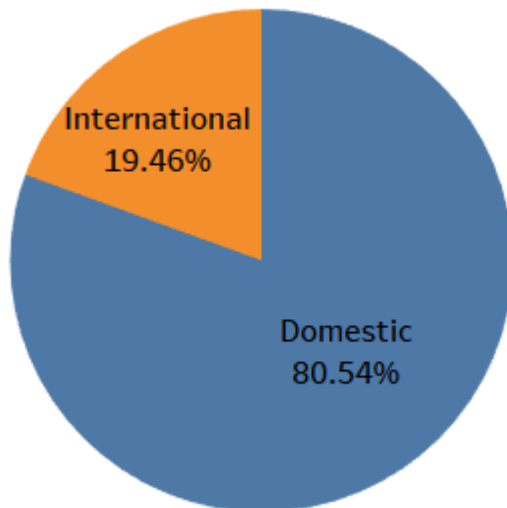


FDA FSMA Technical Assistance Network

Sept 9, 2015 – Sept 15, 2017

International/Domestic Inquiry Count

International/Domestic	Inquiry Count
Domestic	5,212
International	1,259
Grand Total	6,471

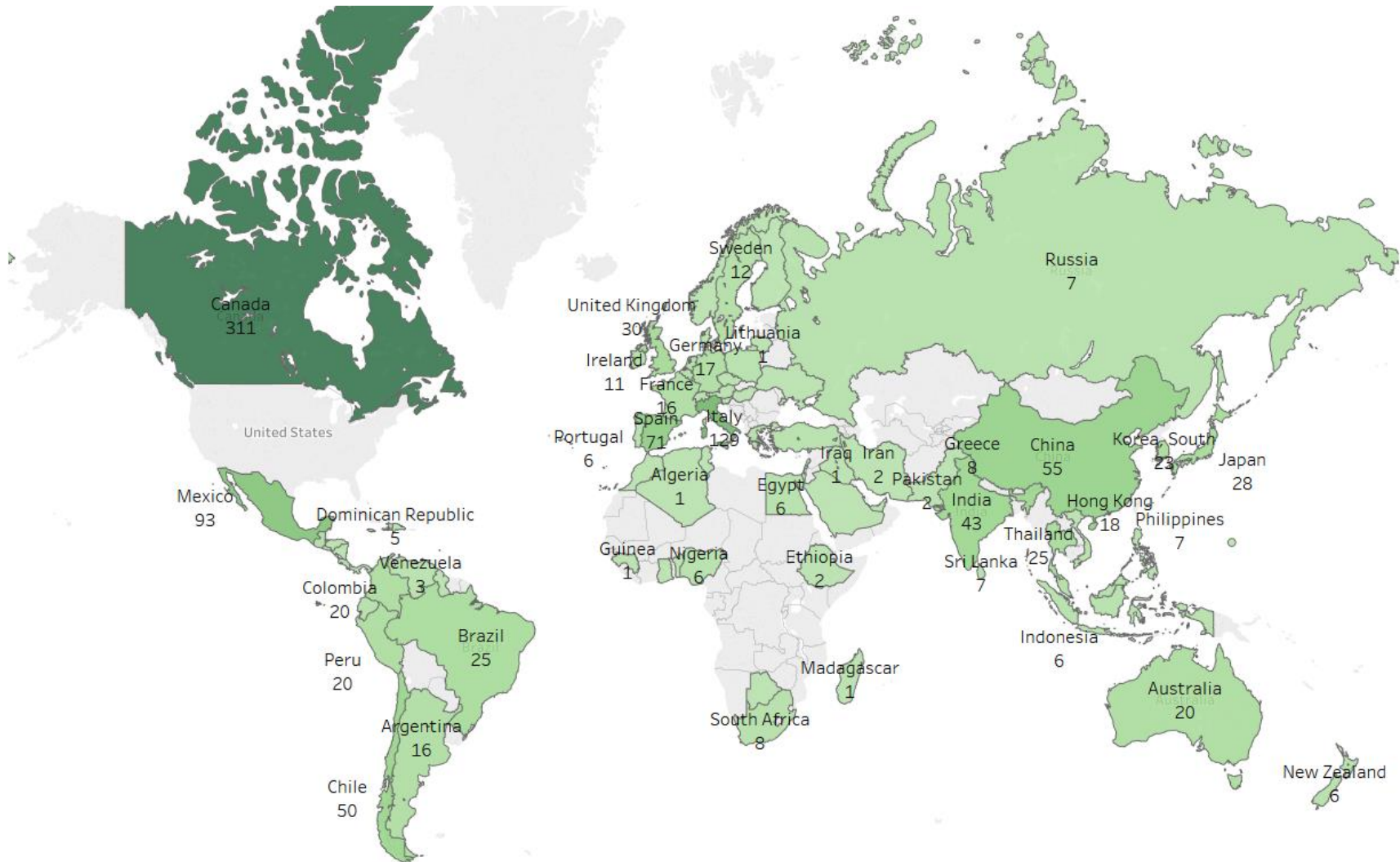


Top International Case Count by Country

Country	Inquiry Count
Canada	311
Italy	129
Mexico	93
Spain	71
China	55
Chile	50
India	43
United Kingdom	30
Japan	28
Brazil	25
Thailand	25
Korea, South	23
Australia	20
Colombia	20
Peru	20

FDA FSMA Technical Assistance Network

Sept 9, 2015 - Sept 15, 2017



Top 5 Spice Related Inquiries

Top 5 Non-FSMA Spice Inquiries:

- Labeling of spice products
- Importing of spice products
- FDA regulations on spice products
- Safety Information
- Complaints about spice products

Top 5 FSMA related Spice Inquiries:

- Labeling of spice products
- Importing of spice products
- How do spice Importers comply with FSMA?
- Is there an exemption list for small businesses?
- FDA regulations on spice products



FDA FSMA Technical Assistance Network

Sept 9, 2015 – Sept 15, 2017

Process Improvements (**internal**):

- Administrators received system licenses
- Meet regularly with FSMA Administrators and Specialists
- Access database with all cleared TAN responses on intranet
- Monthly expanded report showing outstanding inquiries – 30/60/60+ days
- Implementation of a new Agency-wide phone system as well as Single Sign On (SSO) functionality.
- Established internal target days for responses

FDA FSMA Technical Assistance Network

Sept 9, 2015 – Sept 15, 2017

Process Improvements (**external**):

- Auto-responses after 30/60 days
- Summary TAN reports posted on web
- Survey to track effectiveness of web form
- Developed survey to track effectiveness of FSMA responses – Effective December 2017
- Popular topics posted on the web – 75 FAQs

Web Analytics – FSMA TAN Page

Year	Page views	Unique views
2015	5,043	4,343
2016	25,997	21,929
2017	29,300	22,315

Web Analytics – FSMA TAN Page

FSMA Technical Assistance Network (TAN)

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules programs, and implementation strategies.

Have a FSMA Question? [Start Here.](#)

The Technical Assistance Network staff has compiled answers to [common FSMA TAN questions](#). In addition, the complete set of [frequently asked questions on FSMA](#) contains answers to questions on specific provisions of the rule.

Submit Your Question

Didn't find your question above? Please [submit your question](#) to TAN for assistance.

Mail Your Question

If you prefer to mail in your question, please send it to the address below:
Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Note: For Food Safety Preventive Controls Alliance (FSPCA) training and scientific/technical questions, please contact the FSPCA Technical Assistance Network using their web form at <http://www.iit.edu/lfsh/alliance>.

[How the TAN Works](#)

[Additional FSMA Resources](#)

Web Analytics – FSMA TAN Page

FSMA Technical Assistance Network (TAN)



The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Have a FSMA Question? [Start Here.](#)

The Technical Assistance Network staff has compiled answers to [common FSMA TAN questions](#). In addition, the complete set of [frequently asked questions on FSMA](#) contains answers to questions on specific provisions of the rule.

Submit Your Question

Didn't find your question above? Please [submit your question](#) to TAN for assistance.

Mail Your Question

If you prefer to mail in your question, please send it to the address below:

Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Note: For Food Safety Preventive Controls Alliance (FSPCA) training and [scientific/technical questions](#), please contact the FSPCA Technical Assistance Network using their web form <http://www.iit.edu/ifsh/alliance>.

[How the TAN Works](#)

[Additional FSMA Resources](#)

Benefits of TAN

- Inquiries inform guidance and other implementation document development
- Inquirers receive personalized responses about their specific situations
- Identify gaps and needs that can be addressed by web posting, trainings and other communication
- Strengthen relationship with external Alliances through information sharing

Planned Future Improvements

- Continue to reduce response time for inquiries
- More information sharing with Alliances and other partners
- Continue to update FSMA TAN Popular Topics
- Implement Customer Satisfaction Survey

Regulator TAN

- Provides technical assistance regarding FSMA regulations for FDA Investigators before or during the course of an inspection
- The Regulator TAN is an appointment and phone-based system designed to connect investigators with FSMA Subject Matter Experts
- Initially supported the Preventive Control rules and now supporting sprout inspections and FSVP inspections but will ultimately support all FSMA regulations
- Future implementations will include state and local investigators as well

Questions?

