



**CTP
OMBUDSMAN'S
REPORT** *2018-2019*

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The Center for Tobacco Products (CTP) Ombudsman's Office responds to a range of contacts, including complaints from various stakeholders and the public, and facilitates the resolution of disputes between CTP and outside parties. While providing this service, the ombudsman strives to maintain impartiality and neutrality.

This report summarizes the role of the Ombudsman's Office and the complaints, inquiries and disputes the Ombudsman's Office received for calendar years 2018 and 2019, including the number of contacts, their source, subject matter, and status.

OMBUDSMAN IN PRACTICE

What is an ombudsman?

An ombudsman is an impartial, independent person who confidentially receives and investigates complaints and facilitates the resolution of problems. The Ombudsman's Office within CTP follows a code of ethics and operating principles drawn from those established by the Coalition of Federal Ombudsman, the United States Ombudsman Association, and the International Ombudsman Association.

What does the CTP Ombudsman's Office do?

The CTP Ombudsman's Office responds to inquiries and investigates complaints from all parties who contact us, including the tobacco industry, law firms or consultants representing industry, advocacy groups, public and private research institutions, health care providers, and consumers. We also facilitate the resolution of disputes between CTP and external parties and provide general information on the regulatory process. While providing this assistance, the Ombudsman's Office maintains its independence and impartiality, and advocates for fairness.

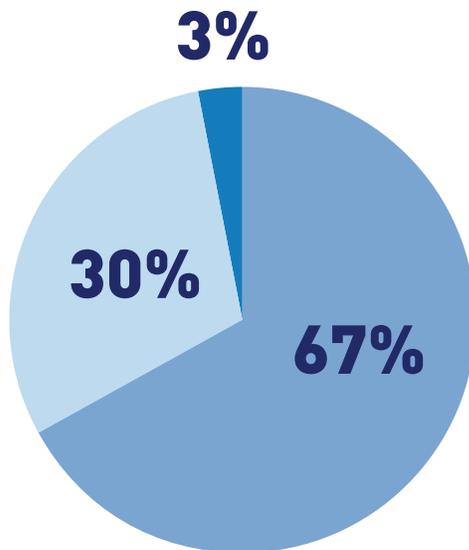
The Ombudsman's Office is available to listen to issues and concerns, even if they do not rise to the level of a complaint or dispute. The Ombudsman's Office also can help to facilitate a dialogue or discussion between outside parties and CTP offices and staff.

Based on the nature of the contacts received from the public, the Ombudsman advises the Office of the Center Director (OCD), where the Ombudsman's Office is located, on ways to assure CTP's procedures, policies and decisions are fair and equitable.

The Ombudsman plays a role in the Internal Scientific Dispute Resolution process when a difference in regulatory opinion between CTP managers and staff arises.

CONTACTS RECEIVED IN 2018

TOTAL: 267



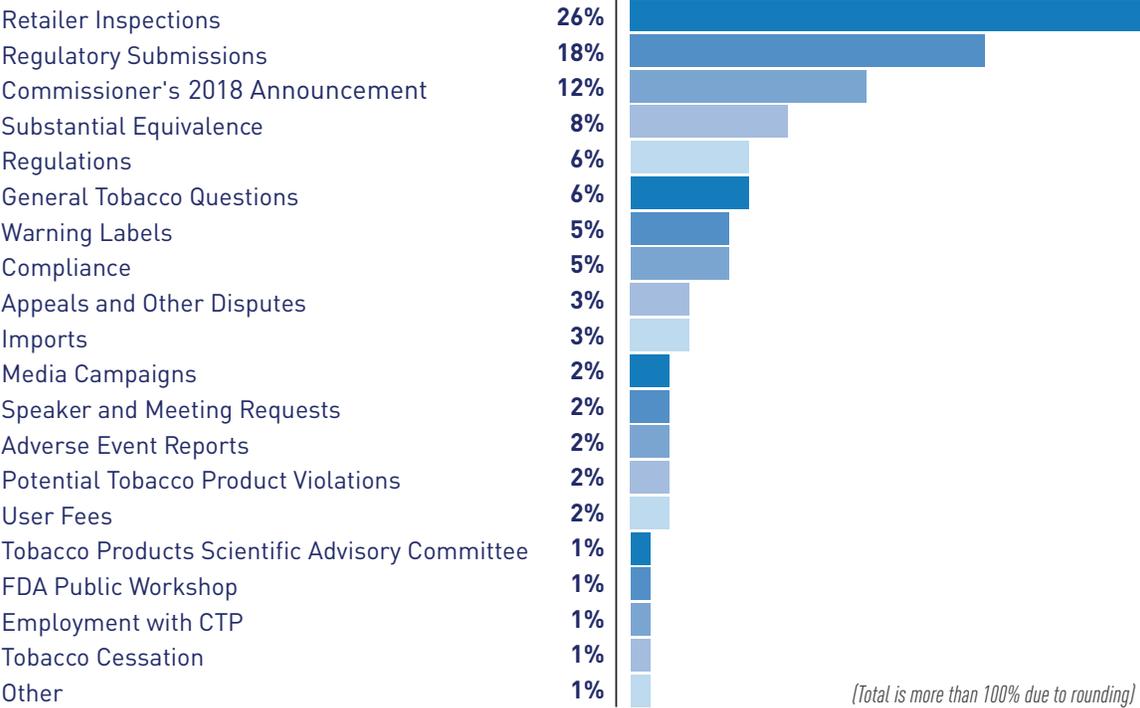
- **Inquiries (180)**
An inquiry may be about an issue that does not rise to the level of a complaint or dispute, such as an inquiry about the regulatory process.
- **Complaints (79)**
A complaint might be an expression of dissatisfaction with a CTP policy or action.
- **Disputes (8)**
A dispute may involve a disagreement with, a challenge to, or an appeal of a CTP decision or action.

CONTACT TRENDS IN 2018

In 2018, the CTP Ombudsman’s Office received inquiries, complaints, and disputes from 267 contacts, up from the 228 received in 2017. From 2017 to 2018, inquiries increased from 130 to 180, complaints decreased from 81 to 79, and disputes decreased from 17 to 8.

Of the contacts received in 2018, 80% were closed. This means the complaint was addressed, the dispute or appeal was resolved, or the inquiry was responded to, referred outside CTP, withdrawn, or had no follow-up by the initiator after one month. This includes those contacts carried over from 2018 and closed in 2019. The closure rate reflects the complexity and breadth of some of the inquiries, many involving more than one office within the Center and numerous follow-up correspondences. In many instances, several phone calls or emails were exchanged with a single contact; however, these follow-up correspondences are counted as a single interaction for the purposes of the report unless substantially different issues were raised.

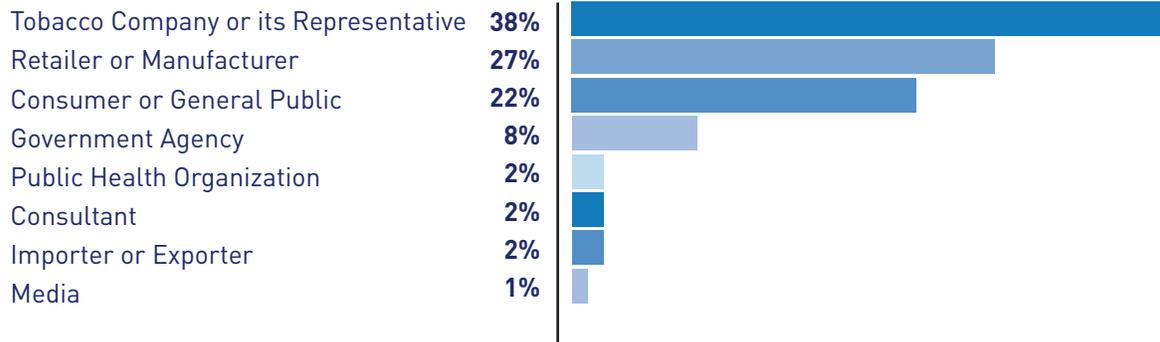
CONTACT TOPIC OF INTEREST IN 2018



The primary topics of interest during 2018 were regulatory submission inquiries, retailer compliance with the Food, Drug, and Cosmetic Act, and former Commissioner Gottlieb’s announcements. As in years past, contacts still had general questions for CTP about tobacco regulation, comments specifically about the substantial equivalence tobacco product application pathway and questions about regulations announced by FDA. There were more inquiries about requirements for warning statements on tobacco product packaging due to compliance deadlines and guidance documents issued in 2018.

Inquiries, complaints and disputes from retailers included general questions about the inspection program and disagreements over the potential violations. In 2018, CTP provided additional information and webinars for the retailer inspection program to help stakeholders understand the inspection program. The increased number of retailer contacts provided an opportunity for the Ombudsman’s Office to interact with many new stakeholders to educate and engage with them about the inspection program.

CONTACT SOURCE IN 2018

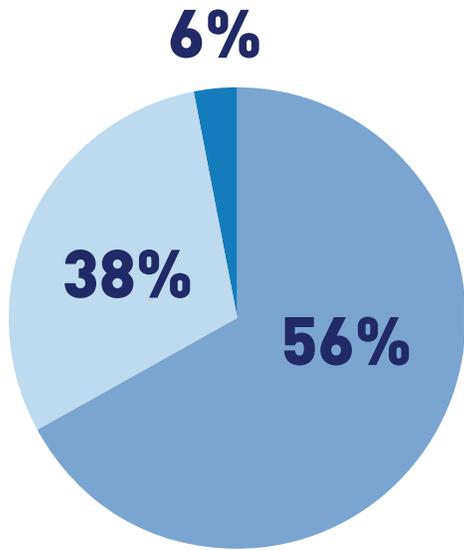


(Total is greater than 100% due to rounding)

As in years prior, tobacco companies and their representatives reached out to the CTP Ombudsman’s Office more frequently than other contacts. The consumer and general public category showed an increase in 2018 (22% in 2018 from 15% in 2017); there was also an increase in contacts from the retailers and manufacturers (27% in 2018 from 11% in 2017). The increase in contacts from these categories show new groups becoming familiar with the Ombudsman’s Office and using us as a resource.

CONTACTS RECEIVED IN 2019

TOTAL: 331



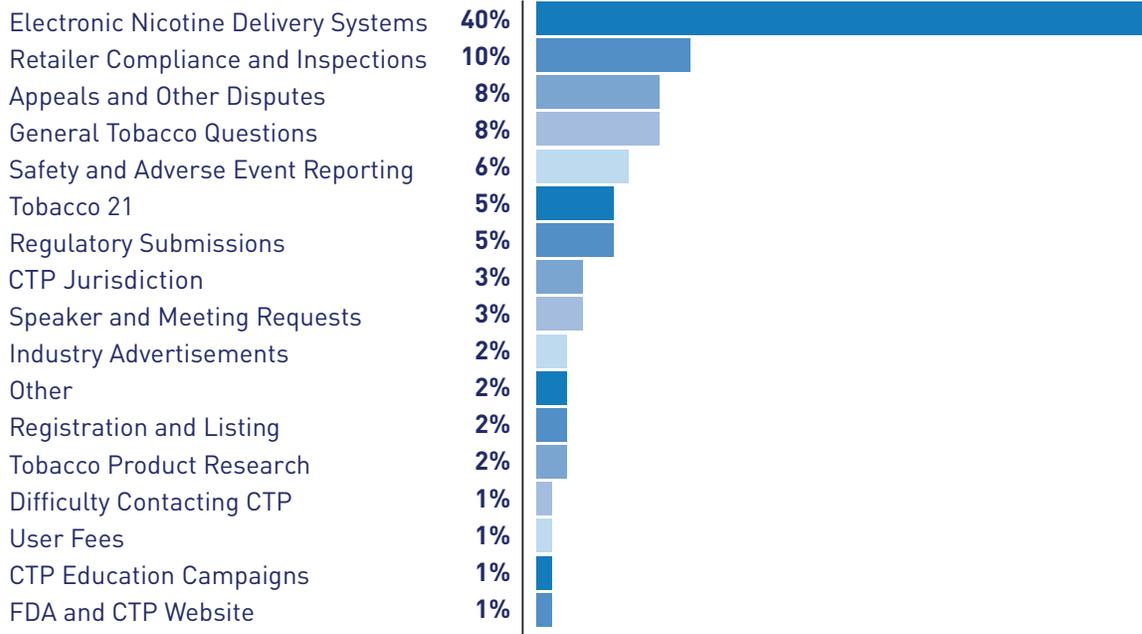
- Inquiries (127)**
An inquiry may be about an issue that does not rise to the level of a complaint or dispute, such as an inquiry about the regulatory process.
- Complaints (185)**
A complaint might be an expression of dissatisfaction with a CTP policy or action.
- Disputes (19)**
A dispute may involve a disagreement with, a challenge to, or an appeal of a CTP decision or action.

CONTACT TRENDS IN 2019

In 2019, the CTP Ombudsman’s Office received inquiries, complaints, and disputes from 331 contacts, an increase from the 267 received in 2018. From 2018 to 2019, inquiries decreased from 180 to 127, complaints increased from 79 to 185, and disputes increased from 8 to 19.

Of contacts received in 2019, 93% were closed. This includes those contacts carried over from 2019 and closed in 2020. In many instances, several phone calls or emails were exchanged with a single contact; however, these follow-up correspondences are counted as a single interaction for the purposes of the report unless substantially different issues were raised.

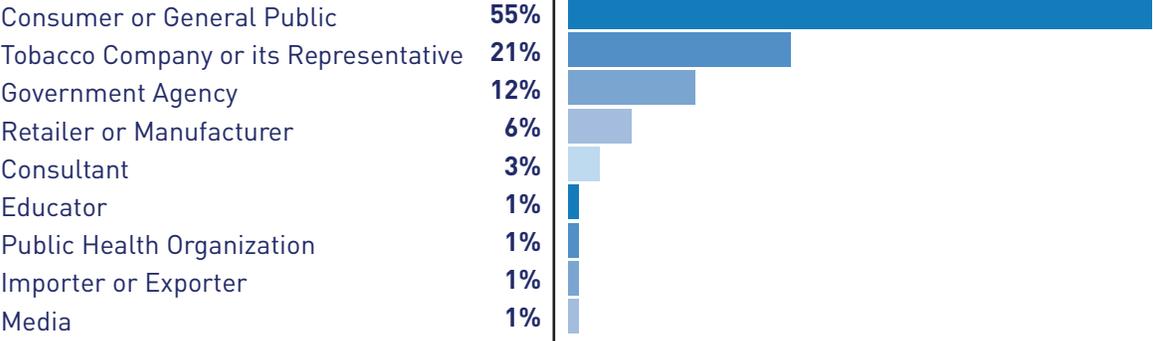
CONTACT TOPIC OF INTEREST IN 2019



(Total is more than 100% due to rounding)

The primary topics of interest during 2019 were regulatory submission inquiries, electronic nicotine delivery systems (ENDS), and Tobacco 21, which is the 2019 legislation that raised the federal minimum age for sale of tobacco products from 18 to 21. There were increased inquiries about tobacco retailer compliance and FDA’s tobacco retailer compliance check inspection program. These contacts gave the Ombudsman’s Office a chance to interact with retailers who were unfamiliar with CTP.

CONTACT SOURCE IN 2019



(Total is more than 100% due to rounding)

For the first time, in 2019 consumers and the general public (55% in 2019 from 22% in 2018) were a bigger share of contacts than tobacco companies and their representatives (21% in 2019 from 38% in 2018). The increase in consumers and the general public show new groups becoming familiar with the Ombudsman’s Office and using us as a resource.

FORMAL DISPUTE RESOLUTION AND APPEALS

The CTP Ombudsman’s Office monitors the resolution of appeals filed pursuant to 21 CFR 10.75. Under 10.75, “an interested party outside the agency may request supervisory review of a decision through the established channels of supervision or review.” Most disputes come from manufacturers who are issued a negative action by CTP, usually a Not Substantially Equivalent order for a tobacco product application.

In 2018, CTP received eight appeals and other formal disputes. We issued one final decision, provided five responses, and the remaining disputes are under review. During 2019, we received nineteen appeals and other formal disputes. We provided eight responses and the remaining disputes are under review. CTP has dedicated staff to assist with processing and managing appeals and formal disputes. For more information about formal dispute resolution options, including how to submit an appeal, please contact the Ombudsman.

SUMMARY

In 2018 and 2019, we received a variety of contacts from tobacco companies (large and small), consumers, the general public, and many others. These groups contacted the CTP Ombudsman’s Office with inquiries, complaints or disputes on a wide range of topics, such as CTP’s regulatory authorities, retailer inspections, ENDS flavor regulation, assistance with youth vaping, and reports of potential tobacco product violations. In the future, we look forward to broadening our engagement with all interested parties.

Why is there a CTP ombudsman?

The Center for Tobacco Products (CTP)

Ombudsman's Office is responsible for responding to a range of contacts, including complaints from various stakeholders and the public, and facilitating the resolution of disputes between CTP and outside parties.

- **Confidentiality**

We will keep what you tell us confidential unless we have serious concerns about your or someone else's safety or unless disclosure is required by law.

- **Impartiality**

We do not advocate for one side or the other, but we do advocate for a fair process.

- **Independence**

We are outside of the business chain of command. The ombudsman reports to the CTP deputy director and has direct access to the CTP director.

- **Informality**

We are here to help. It is important for us to understand what the issue is, to hear what solution you are hoping for, and to figure out what we can do to help.

Why should I contact the CTP ombudsman?

We can help resolve issues by facilitating discussions, brainstorming and evaluating options and resources, offering an impartial perspective, ensuring confidentiality of someone's identity, engaging in shuttle diplomacy, and providing recommendations, among other options.

When should I contact the CTP ombudsman?

Try us when you have not had success with existing CTP processes to address your concerns or because you want to keep your concerns confidential. You are welcome to call or email us any time, but we encourage you to work with your existing CTP contact first.

CENTER FOR TOBACCO PRODUCTS
OMBUDSMAN'S OFFICE



FDA **U.S. FOOD & DRUG**
ADMINISTRATION



301.796.3095



CTPOmbudsman@fda.hhs.gov



<https://www.fda.gov/tobacco-products/contact-ctp/ctp-ombudsman>