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Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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IMPORTED FOODS

Opportunities to Improve FDA's Inspection Program

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GAO

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Human Resources Division

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The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report is in response to your request and later discussions with members of the Subcommittee staff regarding the use of resources for the imported food inspection activities of the Department of Health and Human Services' (HHS's) Food and Drug Administration (FDA). In response to this request, we developed information on how FDA staff responsible for inspecting imported products spent their time and identified areas where the efficiency of inspection activities could be improved.

Background

Under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301), and other laws,[1] FDA is responsible for ensuring that imported FDA-regulated products meet the same safety and labeling standards as domestically produced products. These standards require that all products be safe and honestly labeled to describe their contents. Additionally, foods must be pure and wholesome, and drugs must be effective. Imported products that fail to meet these requirements are considered to be violative and are to be detained at entry locations and must be exported, destroyed, reconditioned, or relabeled to bring them into compliance with federal laws and regulations. FDA reported that food products were being detained for a variety of reasons, including insect, salmonella, and pesticide contamination; labeling problems; or decomposition. Of 23,549 imported food samples that FDA analyzed in fiscal year 1987, 9,362 (about 40 percent) did not meet FDA standards.

FDA's Center for Food Safety and Applied Nutrition is responsible for providing guidance to district offices and monitoring imported food products. Import inspections are carried out by 20 FDA district offices at

[1]The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461), the Tea Importation Act (21 U.S.C. 41-50), and the Public Health Service Act (42 U.S.C. 262-263).

various airports, seaports, and warehouses across the country.[2] Inspections generally consist of two parts: (1) a manual review of all paperwork accompanying products subject to FDA regulation to determine whether physical inspection is warranted based upon a reviewer's assessment of either possible adulteration or mislabeling or both and (2) a physical inspection of products selected as either possibly adulterated, mislabeled, or both. These inspections range from wharf examinations, consisting of a quick, visual examination of products, to collecting samples for laboratory analysis. FDA considers review of entry paperwork an important part of the inspection process, as the compliance of many products is determined on the basis of this review.

Except in high-volume districts, FDA generally does not assign staff exclusively to inspect imported food products. FDA inspection staff are used to inspect both domestic and imported products. FDA allocates available staff-years for import inspection activities among the district offices using a formula based on the proportion of (1) violative goods detained by each office and (2) products subject to FDA regulation entering through locations in each office's geographic area of responsibility. The distribution is weighted to favor offices that receive the highest volume of imports and identify the most violative products. More detailed information on FDA's method of allocating resources for imported food inspection activities is contained in appendix I.

FDA has estimated that, from the mid-1970s to 1987, the annual number of imported entries subject to FDA regulation tripled from 500,000 to about 1.5 million.[3] Of the total entries, about 84 percent are foods with an estimated value of about $20 billion, and the balance are mostly drugs and medical devices.

Of the total time FDA spent on inspection activities in fiscal year 1988, about 18 percent was spent on tasks relating to imported products, including foods, and the remainder was spent on tasks related to domestic products. In the mid-1970s, FDA physically inspected about 20 percent of the imported entries; by 1987 the proportion inspected had decreased to about 9 percent. FDA attributes this reduction primarily to the growth in the number of imports without a corresponding increase in staffing. FDA officials said that the 9-percent inspection level was

[2]Of FDA's 21 district offices across the country, only 20 are involved in import inspection activities. FDA's Newark District Office does not have any responsibility for import inspections.

[3]An entry refers to an article of merchandise brought into the United States by importers or their brokers. An entry may consist of one or more items.

achieved only by reprogramming resources from other areas. According to FDA, physical inspections of imports are the primary means of determining product quality, and the reduction in the proportion of imported products being inspected is of serious concern to the agency.

FDA also reports that the task of inspecting imported foods has become more difficult in the past 10 to 15 years because more imports are being shipped (1) in multiproduct containers, (2) from third world countries with less rigorous quality control standards than those used in the United States, and (3) as ready-to-use consumer goods distributed directly to markets without further opportunity for inspection rather than as raw materials used in domestic manufacturing that is subject to regulatory inspection.

Results in Brief

During an average workweek in 1988, 226 FDA district office staff were involved in import inspection tasks. For these tasks, staff spent, on average, 38 percent of their time in paperwork processing, including the review of entry documents; 13 percent in travel to and from inspection sites; and 22 percent in physical inspections. Of the remaining 27 percent of their time, 14 percent involved clerical support and supervision and 13 percent was spent in meetings. Meetings included discussions with the importing community concerning the status of product compliance. There were wide differences in the time spent on these tasks among the district offices. In travel the range was from 1 to 22 percent, and in paperwork it was from 20 to 57 percent.

FDA may be able to reduce the time spent on paperwork and travel by automating the paperwork review task and centralizing examination locations. Automation has the potential of facilitating the paperwork review task by more quickly selecting problem products or foreign shippers for inspectors, and centralized locations could reduce the time inspectors spend traveling to and from entry locations. If these changes were made, FDA inspectors might have more time available to devote to inspecting imported products.

FDA agreed that automation would help to improve the paperwork review task and told us that it is taking steps to expedite this process. FDA did not believe there would be any benefit to establishing centralized examination facilities and questioned whether it had the authority to do so (see p. 10).

Objectives, Scope, and Methodology

To determine the amount of time FDA district office staff spent on the tasks involved in the inspection process, we asked all such staff to complete a survey of the amount of time they spent on the various tasks. FDA officials identified 17 tasks that were a part of the inspection process. For analysis and reporting purposes, we grouped these tasks into five major categories: (1) paperwork processing, (2) physical inspections, (3) travel, (4) meetings, and (5) supervisory and clerical tasks. Appendix II shows the 17 inspection tasks and how we categorized them.

As our sample period, we selected the workweek beginning on February 29, 1988, which FDA officials agreed was representative of their normal inspection operations.[4] All 226 district office staff who performed import inspection tasks at the 20 district offices during our sample period responded to our questionnaire. As our work covered only inspection tasks, we did not distribute questionnaires to laboratory personnel.

Because in most districts staff are not assigned exclusively to import inspections, we asked them to estimate the time they spent on import inspections during that week. Accordingly, the results of our time survey relate only to the total staff time spent on imported products, including food, which represents the bulk of the products imported.

We performed our work at FDA headquarters in Rockville, Maryland, and Washington, D.C.; the United States Customs Service headquarters in Washington, D.C.; and FDA's and the Customs Service's district offices in Los Angeles, New York, Philadelphia, and San Francisco. We interviewed FDA officials; reviewed agency procedures, policies, and work plans, and studies of imported food inspection activities; and observed import inspection operations.

In carrying out its responsibility of assessing and collecting customs duties and taxes on imported merchandise, the Customs Service also performs inspections of imported products. Therefore, we discussed with Customs officials their inspection procedures and practices to identify any aspects that could be relevant to FDA.

[4]Staff at the Los Angeles district office were surveyed during the workweek of March 7, 1988, because of a partial shutdown of certain supporting laboratory facilities during the workweek of February 29, 1988.

Our field work was completed in March 1989. We conducted our review in accordance with generally accepted government auditing standards.

Efficiency of Import Inspection Program Could Be Improved

The results of our time survey showed that the FDA district offices varied widely in the proportion of time spent on import inspection tasks, as shown in table 1. As indicated in the table, some district offices spent considerably more time than others on the inspection task categories. For example, some offices spent more than twice as much time as others performing physical inspections and processing paperwork on imported products. The differences in the other task categories were even greater.

Table 1: Time Spent on Import Inspection Tasks by Category (Week of Feb. 29, 1988)

Figures in percent

Inspection task category	National average	Range among district offices
Paperwork processing	38	20 to 57
Physical inspections	22	9 to 32
Travel	13	1 to 22
Meetings	13	5 to 32
Supervisory and clerical	14	1 to 32

A breakdown by FDA district office of the amount of time spent on each task category appears in appendix III.

Additionally, FDA's Program Oriented Data System, which compiles information on the various activities performed by district offices, showed that some offices are able to accomplish substantially more inspections in less time than other offices. For example, in fiscal year 1987, the number of wharf examinations performed on all entries, including imported food products, by FDA district offices averaged about 4 per hour. Of the 20 district offices, 3 offices exceeded 6 wharf examinations per hour, while 1 office averaged about 14 per hour.

FDA has completed three studies of its imported food inspection program since 1984. A 1985 FDA regional office study on the productivity of import operations also identified wide variances in the performance level of individual district offices,[5] specifically in the rate at which import entries were detained because they did not comply with FDA's standards. In view of the variations, the study recommended that better

[5]The Productivity/Effectiveness of Import Operations—A System of Measurement—Program Management, FDA Region IX, June 1985.

performing FDA districts be selected for an in-depth study to determine what factors account for their performance. If factors other than local circumstances are at play, the study said, they should be shared with all districts.

According to an FDA official, FDA has not followed up on this recommendation because of differences in workload and procedures among FDA's district offices. The official said that while certain procedures may result in improved efficiency in some district offices, they may not produce similar results in other offices. While the study recognized that local circumstances may account for some differences in the performances of the district offices, it implied that there could be other factors that contribute to the performance differences. Therefore, we believe that an in-depth study would be desirable to determine what practices contribute to better performance and whether they can be implemented systemwide.

A summary of the three FDA studies on the import inspection program and the status of their recommendations appears in appendix IV.

Automating the Paperwork Review Task

The processing of paperwork on imported products accounted for 38 percent of the time FDA staff spent on import inspection tasks. One aspect of the paperwork task—the review of entry documents for imported food products—accounted for 18 percent of total staff time. FDA manually reviewed the paperwork along with FDA notices, alerts, and other information on products and importers relating to 1.5 million entries in 1987.[6] After the paperwork examination, FDA inspectors decide whether to release the product for marketing or to perform a physical inspection.

The Customs Service is also confronted with the task of reviewing the paperwork for millions of entries. To meet the demands of an increasing workload in an environment of budgetary constraints, similar to what FDA now faces, Customs implemented an automated entry review system in 1984. The system selects products for examination based on the enforcement risk associated with a particular product, importer, country-of-origin, or the like. Imported products are automatically selected for detailed examination based on national and local risk-related criteria programmed into the system.

[6]These products represent "formal import entries," which the Customs Service defines as commercial goods valued at over $1,000.

According to an official in the Customs Service's Office of Automated Commercial Systems Operations, Customs has not performed a detailed evaluation of its automated entry review system. He said, however, that the system has enabled inspectors to use their time more productively and concentrate their examinations on high-risk entries.

A 1986 FDA study of import operations found that FDA inspection staff cited paperwork as "one of the most time consuming aspects of their jobs."[7] The study also noted that FDA notices of import alerts and products that were to be automatically detained because of repetitive violations were often outdated by the time they were received by FDA district offices or were too voluminous to be useful. The report recommended that a nationwide, automated data-retrieval tracking system be established that would include information on import alerts, product histories, and detention reports.

In regard to problems concerning import alert notices, FDA officials advised us that in 1987, FDA established the Import Alert Retrieval System, through which abbreviated alert notices are transmitted to district offices.

FDA agrees that to handle increasing workloads, it needs to automate its entry review process. FDA is developing a system, the Import Support and Information System, that eventually will include an automated entry review component. However, because this component cannot be developed until the basic system becomes operational, it is not expected to be available for several years.

Using Centralized Examination Stations Could Reduce Inspectors' Travel

Once the products are identified through the paperwork review for physical inspection, FDA inspectors must travel to and from widespread locations, including airports, seaports, and warehouses, where goods are stored upon arrival. Our time survey showed that FDA inspectors spent an average of about 13 percent of their time traveling to and from locations where products are inspected. Inspectors in one office spent more than 20 percent of their time traveling.

In 1987, the Customs Service established centralized, privately owned and operated examination stations (CESs), where cargo is unloaded for Customs examination and reloaded for subsequent distribution. The

[7] An Organizational Review of Import Operations, FDA's Office of Management and Operations, November 1986.

associated unloading and loading expenses are borne by the importers. Customs claims that the CESs have reduced inspectors' travel time and improved the efficiency of its operations.

Internal Customs Service memoranda on CESs show that they have allowed Customs to (1) reduce the number of inspection sites, (2) reduce the inspection staff, (3) reduce inspector travel time and associated costs, and (4) increase the number and dollar value of cargo seizures. For example:

- In New Jersey and New York, Customs claimed that as a result of consolidating 73 container freight stations into 10 CESs, it reduced staff from about 60 to 20 inspectors and decreased travel-related expenses since inspectors are now permanently stationed at the CESs. For the first 5 months of the CES program, Customs claimed that inspectors made 38 seizures with a total value of over $2 million. During the same 5-month period in the previous year, the inspectors made 12 seizures worth about $500,000.
- In the Los Angeles area, seven CESs are in operation. Customs claimed that as a result of the CESs, it eliminated one inspector position and the need for 12 automobiles. In the year before the establishment of the CESs, Customs claimed that inspectors made 152 seizures of cargo valued at about $9 million. In the first year of the CES program, Customs inspectors made 420 seizures valued at about $30 million.

In a separate review of the Customs Service's airport CESs, we found that while the importing community had initial concerns about the program, it seemed generally satisfied with the CESs after they had begun operations. This was primarily because the program hastened the examinations and release of imported goods.[8] FDA district office officials told us that they have had little experience with CESs. However, FDA's Los Angeles district office has made limited use of Custom Service CESs. According to officials of that district, their experience has been positive, and the concept of centralized inspections is sound.

[8]Air Cargo Imports: Customs Needs to Overcome Concerns to Benefit From Centralizing Examinations (GAO/GGD-88-64, Mar. 31, 1988).

Conclusions and Recommendations

Because of the increasing volume of imported products entering the country and FDA's concern that only a small portion of them are inspected, FDA needs to improve the efficiency of its inspection operations. In this regard, implementing an automated paperwork review system and using centralized inspection locations have potential for contributing to more efficient operations by reducing the amount of time spent on paperwork and travel. Consequently, FDA inspection staff should be able to devote more of their time to inspecting imported food products. Accordingly, we recommend that the Secretary of HHS direct the Commissioner of FDA to

- assess whether some district offices are more efficient and productive than others and, if so, whether the practices of the better performing offices could benefit FDA's nationwide import inspection operations;
- determine whether the automation of the paperwork review task can be expedited; and
- examine the feasibility of expanding the use of centralized facilities in conjunction with Customs for inspection of imported products, especially in offices whose inspectors spend a large percentage of their time traveling.

Agency Comments

As requested by the Chairman's office, we obtained oral comments from FDA officials on a draft of this report. Their comments regarding our recommendations are summarized below.

FDA concurred with our recommendation to determine whether some of its district offices were more efficient than others and whether certain office practices could produce systemwide benefits. FDA said that before implementing this recommendation, it would conduct its own study of the time spent by its staff on inspection tasks. According to FDA, the study will collect additional information that was beyond the scope of our study and will allow for appropriate decisions to be made.

FDA also concurred with our recommendation on the need to expedite the automation of the paperwork process. FDA said that it would take action to see that this occurs to the extent that legal and other requirements allow.

FDA disagreed with our recommendation to explore the feasibility of establishing centralized facilities to store imported products for inspection. FDA noted that it (1) did not have legal authority to require importers to deliver products to central facilities and (2) did not see any advantage to stationing personnel at these facilities.

FDA officials told us that FDA could not require importers to transport products to centralized facilities. We agree. However, section 801 of the Food, Drug, and Cosmetic Act, as amended, provides, among other things, that the Secretary of the Treasury shall deliver to HHS, upon request, samples of imported food for examination to assure it has been processed under sanitary conditions. FDA acknowledged that it uses this authority to work with Customs in inspecting imported samples at existing centralized examination stations. Accordingly, we would propose that FDA examine the feasibility of expanding its use of centralized examination facilities in conjunction with Customs. Such expanded use would be accomplished under existing authority.

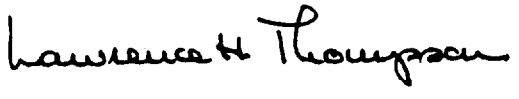
FDA's other objection to adopting the CES concept was based on its belief that stationing personnel at CESs offered no advantage over its present method of having inspectors travel to entry locations to inspect imported food products. FDA noted that CESs are created through a contractual arrangement with several facilities to avoid giving an unfair economic advantage to any one facility. Thus, FDA said that since it could not station personnel at these facilities and products would not be assigned to a single facility, FDA staff would still be required to travel to various locations to inspect products.

We have not recommended that FDA personnel be stationed at CESs. We agree that even with CESs, FDA staff might have to travel to various inspection locations; however, Customs CES locations are generally determined in consultation with the importing community to minimize travel. Moreover, with CESs the staff would travel to fewer locations. A good example is Customs' consolidation of 73 examination locations in New Jersey and New York into 10. By contrast, according to FDA's Deputy Director of the Office of Regulatory Resource Management, FDA inspectors currently must travel to several hundred locations in the New York area, including Customs CESs, to inspect imported food products. Clearly, it would seem that FDA could also benefit from such consolidation. Consolidation could help to alleviate FDA's concern about the dwindling number of imported food products being inspected by making more time available for staff to perform this task.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 10 days from its issue date. At that time, copies will be sent to the cognizant Senate and House committees and subcommittees; the Secretary of HHS; the Secretary of the Treasury; the Commissioner of FDA; and the Director, Office of Management and Budget, and we will make copies available to other interested parties upon request.

This report was prepared under the direction of Janet L. Shikles, Director of National and Public Health Issues. Other major contributors are listed in appendix V.

Sincerely yours,



Lawrence H. Thompson
Assistant Comptroller General

Contents

Abbreviations

CES	centralized examination station
FDA	Food and Drug Administration
GAO	General Accounting Office
HHS	Department of Health and Human Services
ORA	Office of Regulatory Affairs

Basis for Allocating Staff Resources to District Offices for Import Inspection Activities

FDA uses a uniform method to allocate staff resources to its centers and district offices. Approximately 14 months before the beginning of a target fiscal year, the Office of Regulatory Affairs (ORA) begins planning for the number of district office staff resources to be allocated for an activity, such as import inspections. ORA, which provides coordination and guidance to FDA's district offices, provides each of FDA's five operating center directors with the total number and type of district office staff-years that will be available during the target year nationwide. Each center director specifies the number of staff-years that will be devoted to individual programs, such as imported foods.

Using the centers' forecasts, ORA develops a work plan specifying the number of staff-years individual district offices can expend on each program during the upcoming fiscal year. According to FDA, this plan is intended to provide field managers with anticipated staffing levels and output goals to carry out FDA's mission. The goals are intended to represent statements of intent rather than rigid requirements and allow field managers the flexibility to accommodate emergency situations and unforeseen changes in program priorities.

Staff-year resources for the import program are allocated to the district offices based upon the following formulas.

- Seventy-five percent of the staff-years available are distributed based on the detention history of each district office.
- Twenty-five percent of the staff-years available are distributed based on the historical number of entries received in each district office.

Conversion of 17 Inspection Tasks Into Five Categories

Paperwork Processing	Entry reviews Paperwork—sample Paperwork—other
Physical Inspections	Locating containers Waiting for containers Locating packages Walk-by inspections Wharf examinations Sample collections Documentary samples Witnessing destruction of export
Travel	Travel
Meetings	Internal—FDA External
Supervisory and Clerical	Supervision Clerical Other

Time Spent by FDA Staff on Import Inspection Tasks by Category

Figures in percent

District	Paperwork processing[a]	Physical inspections	Travel	Meetings[b]	Supervisory and clerical
National average	38.0	22.2	12.7	13.1	14.0
Atlanta	19.8	22.5	10.6	30.2	16.9
Baltimore	40.8	10.9	9.9	15.6	22.8
Boston	31.7	25.2	22.0	9.6	11.5
Buffalo	30.9	26.2	11.0	13.3	18.6
Chicago	41.5	21.6	14.0	10.5	12.4
Cincinnati	56.6	9.0	6.6	10.8	17.0
Dallas	37.5	21.0	7.5	20.5	13.5
Denver	44.3	15.7	11.4	28.6	0
Detroit	25.0	20.5	7.5	27.6	19.5
Kansas City	28.6	22.5	4.9	14.3	29.7
Los Angeles	35.9	20.7	10.8	17.8	14.8
Minneapolis	40.1	13.5	1.0	32.4	13.0
Nashville	53.6	22.1	8.3	12.1	3.8
New Orleans	27.4	32.2	7.8	14.8	17.8
New York	39.7	22.8	19.1	6.0	12.5
Orlando	38.6	26.3	9.4	14.6	11.2
Philadelphia	56.2	22.4	8.5	9.5	3.3
San Francisco	38.1	27.8	17.3	5.4	11.4
San Juan	44.4	8.8	6.1	9.2	31.5
Seattle	34.5	24.9	13.5	17.3	9.8

[a]The review of entry documents accounted for 18 percent of the total staff time spent on this task.

[b]Time spent in meetings included discussions with importers concerning product compliance with FDA standards.

Prior FDA Studies of Import Operations and Status of Recommendations Pertinent to GAO's Review

FDA officials identified three studies on import operations that FDA had completed since 1984. The recommendations resulting from each study and FDA's actions on them are discussed below.

FDA study	Recommendation	FDA action
An Organizational Review of FDA's Import Operations (Nov. 1986)—analyzed the organizational structure and relationship between headquarters and field components of FDA's import operations.	Assure that the American public is adequately protected by more closely monitoring and taking enforcement action against importers who repeatedly violate regulations. This could be accomplished by:	
	Establishing a nationwide list of importers who have continually violated FDA regulations and target them for more frequent inspections.	Partially implemented. Although FDA found it was not feasible to establish a nationwide list, it did establish programs to identify problem products and importers.
	Establishing procedures to alert FDA of problem importers and place them under automatic detention.	Implemented. FDA strengthened its internal procedures for placing problem importers and products under detention.
	Reviewing products under automatic detention to determine which products or manufacturers require more stringent enforcement action.	Implemented. FDA established a program to periodically review all import alerts to focus on problem areas.
	Establishing a direct, electronic link between FDA and the Customs Service.	Not implemented. FDA, however, plans to establish such a link when its automated import information system is on line.
	Determining which products need only periodic surveillance.	Implemented. FDA reviews imported products to determine those in need of more scrutiny than others.
	Increasing follow-up of rejected entries.	Implemented. Although FDA believes that this is a Customs responsibility, it developed a program to insure that adequate corrective actions have been taken on rejected entries.
	Establish a nationwide, automated data system to include automatic detentions, import alerts, detention reports, and product histories.	In process. FDA has automated the alert notification system. A pilot test of the first phase of the complete system is scheduled for November 1989.
	Determine which products have a high rate of compliance and exempt them from preparing FDA entry forms.	Not implemented. FDA rejected this recommendation because it does not want to exempt any product from potential inspection.
	Establish resident posts at O'Hare and John F. Kennedy Airports to reduce travel.	Implemented. A resident post was established at John F. Kennedy Airport, and one person was permanently stationed at O'Hare Airport.

(continued)

FDA study	Recommendation	FDA action
	Establish agreements with brokers, importers, and container yard operators to require that products not be released without FDA clearance. Detain products from importers who are uncooperative.	Not implemented. FDA does not believe that the release of merchandise is a problem because most shipments are moved intact to storage facilities within the immediate area.
	Develop a system that identifies the total volume of FDA-regulated products that enter the country through each port of entry.	In process. FDA's planned automated information system is to provide these data.
A Procedure to Allocate Field Import Program Resources (Oct. 1985)—examined FDA's procedures for allocating resources to the field for import operations and developed alternative allocation methods.	Allocate resources based on the number of detentions and entries.	Implemented. FDA adopted this allocation method in fiscal year 1987.
The Productivity Effectiveness of Import Operations (June 1985)—found that wide variations existed in detention rates among FDA district offices and developed a system to measure differences in productivity and effectiveness.	Study top-performing districts to determine whether factors that account for their performance can be used by all districts.	Not implemented. FDA believes that efficient practices used by some offices may not achieve the same effect elsewhere.

Major Contributors to This Report

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