U.S. Office of Personnel Management Office of Merit Systems Oversight and Effectiveness Classification Appeals and FLSA Programs

Dallas Oversight Division 1100 Commerce Street, Room 4C22 Dallas, TX 75242

Classification Appeal Decision Under Section 5112 of Title 5, United States Code

Appellant: [appellant]

Agency classification: Consumer Safety Officer

GS-0696-12

Organization: Resident Post

District Office [location]

Food and Drug Administration

Department of Health and Human Services

[city, state]

OPM decision: Consumer Safety Officer

GS-696-12

OPM decision number: C-0696-12-02

/s/ Bonnie J. Brandon

Bonnie J. Brandon

Classification Appeals Officer

8/16/99

Date

As provided in section 511.612 of title 5, Code of Federal Regulations, this decision constitutes a certificate that is mandatory and binding on all administrative, certifying, payroll, disbursing, and accounting officials of the government. The agency is responsible for reviewing its classification decisions for identical, similar, or related positions to ensure consistency with this decision. There is no right of further appeal. This decision is subject to discretionary review only under conditions and time limits specified in the Introduction to the Position Classification Standards, appendix 4, section G (address provided in appendix 4, section H).

Decision sent to:

[appellant's name and address]

Acting Director of Personnel Operations III Office of Human Resources Management Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Deputy Assistant Secretary for Human Resources Department of Health and Human Services HHH Building 200 Independence Avenue, SW. Room 536E Washington, DC 20201

Introduction

On April 26, 1999, the Dallas Oversight Division of the U. S. Office of Personnel Management (OPM) accepted a classification appeal from [the appellant]. [The appellant's] position is classified as Consumer Safety Officer, GS-696-12. However, the appellant believes the classification should be Consumer Safety Officer, GS-696-13. [The appellant] works in the [activity], Food and Drug Administration, Department of Health and Human Services, [city, state].

We have accepted and decided this appeal under section 5112(b) of title 5, United States Code (U.S.C.). This is the final administrative decision on the classification of the position subject to discretionary review only under the limited conditions and time outlined in part 511, subpart F, of title 5, Code of Federal Regulations.

To help decide this appeal, a Dallas Oversight Division representative conducted a telephone audit of the appellant's position. The audit included interviews with the appellant and her immediate supervisor. In reaching our classification decision, we reviewed the audit findings and the information of record furnished by the appellant and her agency, including her official position description [number]. The appellant's supervisor has provided a signed statement certifying that the appellant is performing the duties outlined in her position description. We find the official position description to be an accurate summary of the appellant's duties and responsibilities and to be adequate for classification purposes.

General issues

The appellant, who states that her position description is accurate to some extent, compares her work with a GS-13 Consumer Safety Officer position description, number 97F010. She believes that some of her work equates to the GS-13 level and makes up at least 25 percent of her time. She also indicates that her position description does not adequately reflect the full degree of responsibility for investigative and advisory duties that she performs. Further, she states that she has served on several details, including details to supervisory and higher graded positions, and believes that consideration should be given to the complexity of work performed during those details. The appellant also indicates that the impact of her work extends beyond the geographic location of her position in [a specific city]. However, volume of work, work quality, work efficiency, or temporary duties or duties performed in another employee's absence cannot be considered in determining the grade of the position. By law, we must classify positions solely by comparing the current duties and responsibilities of the job to OPM standards and guidelines (5 U. S. C. 5106, 5107, and 5112). Comparison to standards is the exclusive method for discussing positions; therefore, we cannot compare the appellant's position description to others as a basis for deciding this appeal.

Position information

The appellant is the Consumer Safety Officer (Resident-in-Charge) for the [city, state] Resident Post, Food and Drug Administration (FDA). The appellant is responsible for inspection and

compliance functions within her geographic jurisdiction. She is responsible for maintaining the Resident Post's facilities and equipment, planning work activities, and resolving problems that occur daily at this location. Her responsibilities include enforcing and obtaining compliance with Federal laws and regulations protecting the public from contaminated, dangerous, defective, or mislabeled foods, drugs, cosmetics, medical devices and equipment, and other hazardous substances. The appellant independently inspects and prepares reports regarding the conditions of plants and facilities whose products are subject to regulation by the Food and Drug Administration. She obtains information on the manufacturing practices and quality control processes and collects product samples for analysis to determine compliance with regulatory requirements. She conducts investigations of reported illnesses, injuries, or deaths resulting from contaminated, defective, or otherwise unsafe products and devices. The appellant also investigates fires, floods, and other disasters requiring immediate attention. She provides training to other agency employees on the various aspects of the FDA's enforcement activities. She represents the FDA in dealing with the public, State, and local officials, industry representatives, and other segments of the Federal Government, etc., located within the geographic area of residency. She assists U. S. Attorneys pursuing legal action against violators by assisting in case preparation. The appellant's position description and other material of record furnish more information about her duties and how they are performed.

Series determination

The agency has classified the position in the Consumer Safety Series, GS-696, and the appellant does not question this determination. This series covers professional positions concerned with enforcing the laws and regulations protecting consumers from foods, drugs, cosmetics, fabrics, toys, and household products and equipment that are impure, unwholesome, ineffective, improperly or deceptively labeled or packaged, or in some other way dangerous or defective. Knowledge of various scientific fields (e.g., chemistry, biology, pharmacology, and food technology) is required. Consumer safety officers identify substances and sources of adulteration and contamination. They also evaluate manufacturing practices, production processes, laboratory analyses, quality control systems, and clinical investigation programs. We concur that this position is properly classified in the Consumer Safety Series, GS-696.

Title determination

The title of Consumer Safety Officer is authorized for nonsupervisory positions that meet the definition outlined in the GS-696 Consumer Safety Series. Neither the agency nor the appellant disagrees with the title of the appealed position. Consumer Safety Officer is the appropriate title for the position.

Standard determination

The appellant's position is properly graded using the Position Classification Standards for the Consumer Safety Series, GS-696.

Grade determination

The GS-696 standard uses two factors to distinguish between grade levels: *nature of assignment* and *level of responsibility*. We will address the duties and responsibilities of the appellant's position with respect to these two factors.

Nature of assignment

This factor deals with (1) the complexity of the assignments; (2) the purpose and urgency of inspections and investigations; and (3) the attitude of the establishment management and their history of violations. These elements are important in determining the level of knowledge, skill, and ability required to complete assignments.

- (1) The complexity of assignments is a significant factor at each grade level. Warehouses, distributors, and retail outlets are ordinarily among the simplest to inspect. Production establishments are more difficult, requiring more indepth knowledge of commodities and additional knowledge of manufacturing processing techniques. The complexity of assignments depends on:
- the inherent complexity of products--their ingredients and chemical and physical characteristics, their stability and susceptibility to contamination, and the importance of purity and uniformity;
- the volume and diversity of products--the variety of ingredients and the variety of sophistication of equipment and processes; and
- the sophistication and complexity of quality assurance systems--laboratory analyses of raw materials and products, laboratory and clinical testing, scheduling of operations, cleaning and maintaining equipment and facilities, cross-checking steps in progress, and handling and storing of ingredients, products, labels, containers, etc.
- (2) The purpose and urgency of assignments range from routinely scheduled inspections to special investigations; from limited inspection for specific information about a phase of an operation to complete inspections of total operations; and from poor manufacturing practices or technical violations that present no immediate hazards to serious health hazards that must be identified and removed immediately.
- (3) The attitude of the establishment management and their history of violations are bases for judging the likelihood of encountering violations, whether they might be serious or intentional violations, and the probable difficulty of obtaining accurate and adequate information.

The GS-696 standard describes two types of Consumer Safety Officer assignments typical of the GS-12 level. The first type of assignment requires the use of indepth knowledge of an industry or class of commodities, including an excellent knowledge of raw materials, products, manufacturing practices, and related problems of the industry. The employee is required to keep abreast of the latest technological changes and conditions of firms in their districts and related firms and activities in other districts. Assignments frequently involve new problems that are lacking in well-defined guidelines and precedents. The employee plans, coordinates, and conducts inspections and investigations with numerous complications, where timeliness, skill, and tact are critical. The Consumer Safety Officer plans and serves as team leader conducting intensive investigations of major manufacturers. The GS-12 employee coordinates the work of the team that may include other consumer safety officers, inspectors, and scientific personnel (typically chemists and microbiologists) and ensures that the final report and recommendations represent a unified view. The employee also coordinates the district's participation in nationwide investigations of major crises affecting the health and safety of the general population and involving major industries.

The second type of assignment involves situations where, in addition to the full range of assignments described at the GS-11 level, the GS-12 employee is the sole or senior Consumer Safety Officer at a resident post. The GS-12 employee conducts the full range of inspections and investigations within the geographical area covered by the post. The also employee maintains liaison, plans, and coordinates activities with State and local public health officials, representatives of other Federal agencies, marshals, U.S. Attorneys, and court officials. The GS-12 employee evaluates the urgency and seriousness of reports of consumer injuries and deaths and complaints of violative products. The employee responds to inquiries from industry and consumers requiring scientific and technical advice. At the GS-12 level, the employee uses judgment and a good knowledge of agency policies and priorities to set priorities for handling many unscheduled matters that come directly to the office. As an agency representative, the GS-12 Consumer Safety Officer informs the general public about agency programs, violative products, and legal actions.

At the GS-13 level, the Consumer Safety Officer performing compliance work applies an extensive knowledge of the pertinent laws and regulations, precedent cases, procedures for taking legal actions, and the nature and extent of evidence required to support legal actions. In addition, the employee utilizes a thorough understanding of agency policies and priorities, and the provisions and intent of new programs and regulations that are not well-defined, to make judgmental decisions regarding legal actions and give advisory opinions. By comparison, GS-12 employees perform compliance work in a developmental capacity and give advisory opinions on well-established programs and regulations.

At the district office level, the GS-13 Consumer Safety Officer is the primary source of expertise within the geographic area covered on the interpretation of the laws, regulations, and programs. The employee advises managers, inspectors, and laboratory analysts on a wide range of regulatory questions; reviews reports of inspections, investigations, and laboratory analyses for violations; determines the sufficiency of the evidence (requesting further investigation where necessary); and

recommends further legal action. The Consumer Safety Officer independently acts upon the full range of violations occurring in the district, including those that involve emergency situations, uncooperative industry officials, ambiguous or dubious evidence, and lack of precedents and guidelines. By comparison, GS-12 employees primarily deal with routine compliance issues and problems for which precedents and guidelines have been established.

In recommending legal actions, GS-13 employees consider the seriousness of violations, the hazards involved, the violator's history, precedent court decisions, and consumer interest, in addition to the legal and regulatory requirements.

Illustrative assignments typical of the GS-13 level follow:

- prepare support for legal contests, the outcome of which will have a significant impact on major firms regulated by the agency;
- advise industry and agency management on the interpretation, intent, or impact of new programs, legislation, court decisions, and scientific findings; and
- develop legal cases that are complicated by (1) varied, inconsistent, or insufficient evidence and information; (2) extreme public interest; (3) financially powerful industries; or (4) new or previously unknown hazards.

The appealed position meets the GS-12 level. As the [city] Resident-in-Charge, the appellant is responsible for independently conducting inspections and investigations of multiple businesses and facilities involved in the manufacture, processing, distribution, storage, or selling of a broad category of products. As at the GS-12 level, the appellant's work is characterized by application of an indepth knowledge of a class of commodities, for example, biologics, drugs, seafood, and medical devices. The appellant utilizes a knowledge of raw materials, products, manufacturing practices, and industry concerns to complete assignments within her geographical jurisdiction. Her responsibility is to ensure that products conform with agency enforced regulatory requirements for purity, effectiveness, labeling, packaging, and safety. The appellant's activities frequently entail inspections and investigations of products having unusual manufacturing processes, diverse and varying food standards, additives or ingredients, quality control processes, and relatively complex labeling requirements. She conducts investigations in instances of illness, injury, or death involving foods, drugs, devices, and other agency-regulated products. The appellant also has responsibility for inspecting facilities containing regulated products following disasters such as fires, floods, storms, etc., to ensure the products are safe for distribution. The appellant's assignments fluctuate due to national interest and congressional funding for specific program areas. Although there is currently strong emphasis on FDA regulated firms meeting seafood hazard analysis and critical control point systems, the [city] area has a limited number of seafood firms. During the last year, the appellant spent a substantial amount of her time on assignments involving biomedical research and blood bank activities. While performing these assignments, the appellant may encounter hostile and/or uncooperative management. Most of the

violators encountered by the appellant will plea bargain or will not contest seizures when adequate evidence is provided. The appellant has handled cases where licenses have been revoked. However, the inspections and investigations handled by the appellant have not resulted in extensive legal actions involving court testimonies.

The GS-13 level is not met. The appellant does perform a variety of compliance work that requires an extensive knowledge of laws, rules, and legal procedures. Assignments which may appear to initially be one level of complexity may become more or less complex due to unpredictable variables, resulting in assignments being handled sometimes above and sometimes below a particular grade level. For example, completing similar assignments that differ in the number and type of violation and subsequent court actions may affect the grade level. While the appellant is well-respected and considered an authority by many managers, inspectors, law enforcement officials, and others who frequently contact her for advice, the type of advice she provides is comparable to the advisory opinions described at the GS-12 level. The appellant follows established objectives and legal precedents for much of what she encounters. Advice on new programs and regulations that are yet to be well-defined is available at the district level. The appealed position does not fully meet the criteria at the GS-13 level and, therefore, must be credited with the GS-12 level.

Level of responsibility

This factor deals with (1) the degree of supervision received; (2) the adequacy and specificity of instructions and guidelines; and (3) the nature and significance of personal contacts, recommendations, and decisions.

GS-12 consumer safety officers plan and conduct inspectional and investigative assignments after receiving instructions regarding objectives and priorities. Since many GS-12 inspectional assignment deal with new or unusual commodities and manufacturing practices, inspectional programs and guidelines in the assigned area are frequently outdated, too broad, or in some other way inadequate. The lack of adequate guidelines requires GS-12 employees to develop new inspectional approaches and methodologies appropriate to the assignment at hand. GS-12 employees independently resolve most inspectional and investigative problems they encounter. They refer to their supervisors, however, extremely critical or controversial policy matters or cases that require expeditious handling. They consult with laboratory analysts on problems regarding new or unusual formulations, laboratory analytical methods, or microbiological contamination.

Letters, reports, and recommendations that GS-12 employees prepare are generally assumed to be technically accurate. Supervisory review of completed work is in terms of adequacy of supporting data, soundness of judgment, and conformance with policy. Supervisors generally accept the recommendations of GS-12 employees regarding new inspectional approaches and methodologies, the extent and seriousness of violations, and the acceptability of voluntary corrective action. The Consumer Safety Officer at this level is frequiently responsible for

initiating and maintaining effective relations with State and local public health officials, representatives of other Federal agencies, industry officials, and consumer interest groups to explain and interpret established agency policies and priorities and to evaluate new manufacturing or inspection plans.

GS-13 consumer safety officers in the district office carry out their compliance assignments with a substantial degree of independence. They receive guidance regarding agency-wide policies, priorities, and positions on new or controversial issues. They consult project managers, scientists, and attorneys at the headquarters level on extremely complex or controversial legal or technical problems. By comparison, GS-12 consumer safety officers receive guidance on nonroutine compliance problems or issues. For many of the issues and questions that are directed to GS-13 employees, precedents and guidelines are inadequate. GS-13 employees rely upon their scientific backgrounds and understanding of broad legislation, policy statements, and program definitions to formulate recommendations and decisions. They recognize and convey to the agency headquarters serious problems and issues where policy decisions are needed. Decisions and recommendations of GS-13 employees typically receive administrative review within the district office. At the agency headquarters, decisions and recommendations of the district employees may be more closely reviewed for policy implications, impact on agency-wide activities, and priority for expenditure of resources.

GS-13 consumer safety officers have frequent contacts with U.S. Attorneys and court officials regarding legal actions. They hold hearings with industry officials. They also have contacts with recognied scientific and industry experts regarding precedent-setting legal actions or issues affecting major industry practices.

The GS-12 level is met. The appellant independently plans and carries out her own assignments based on established objectives. She is responsible for resolving the difficult, complex, or sensitive problems encountered during the normal course of her work. The appellant inspects and investigates large and small firms that include unusual features or products. Because some guidelines used by the appellant may be outdated, she adapts available established methods and procedures to determine if a firm is in compliance with regulatory requirements. The appellant develops ways to deal with new or unusual situations and shares ideas with management and other inspectors. The reports of findings and recommendations prepared by the appellant are considered technically sound. Supervisory review of completed work is primarily in terms of compatibility with agency policy and other work and effectiveness in achieving expected results.

The GS-13 level is not met. The appellant is responsible for independently carrying out her assignments. However, she does not operate with the degree of independence on matters found at the GS-13 level. At this level, guidance is typically provided only on agency-wide policies, priorities, or positions on new or controversial issues. The GS-13 Consumer Safety Officer assignments are of such magnitude that recommendations receive an administrative review within the district office while decisions and recommendations of district employees may be more closely reviewed at the headquarters level for policy implications, impact on agency-wide activities, and priority for expenditures of resources. The GS-13 Consumer Safety Officer relies on an indepth knowledge of scientific areas, legislation, and agency policy to develop recommendations and

make policy decisions. In contrast, the appellant is typically concerned with guidance pertaining to issues that bear on whether a business or facility is in conformance with or in violation of regulations and the potential actions or steps that need to be taken.

Decision

The position is properly classified as Consumer Safety Officer, GS-696-12.