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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

■

ADMINISTRATION AND ENFORCEMENT OF CERTAIN CIVIL RIGHTS LAWS AND AUTHORITIES

Consolidated Procedural Rules

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

[45 CFR Part 81]

CONSOLIDATED PROCEDURAL RULES FOR ADMINISTRATION AND ENFORCEMENT OF CERTAIN CIVIL RIGHTS LAWS AND AUTHORITIES

Notice of Proposed Rulemaking

Purpose of Part 81. The Office for Civil Rights of the Department of Health, Education, and Welfare proposes to issue a new Part 81 to the Departmental Regulation to establish a uniform procedure for enforcement of the various nondiscrimination requirements which are applicable to programs administered by the Department and for which responsibility has been delegated to the Director of that Office. These enforcement procedures will apply to title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) as implemented by 45 CFR Part 80; title IX of the Education Amendments of 1972 (20 U.S.C. 1681, et seq.) as implemented by 45 CFR Part 86; sections 799A and 845 of the Public Health Service Act (42 U.S.C. 295h–9 and 298b–2); section 504 of the Rehabilitation Act of 1972 (29 U.S.C. 794); section 407 of the Alcohol and Drug Abuse and Treatment Act of 1972 (42 U.S.C. 1173); and section 321 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. 4587).

The current Part 81 (45 CFR Part 81) was issued in November 1967, under 5 U.S.C. 301 and 45 CFR 80.9(d), the latter being a provision of the Department's regulation implementing title VI of the Civil Rights Act of 1964. At that time, title VI was the only major civil rights enforcement program being administered by the Department, and the regulation was expressly tailored to meet the Department's needs in a busy but relatively limited area. Since that time, numerous authorities have been enacted by Congress in the civil rights area and the Department's responsibilities with regard to enforcement of these statutes as well as its duties under Executive Order 11246 have likewise increased greatly.

At the present time most of the grantees and contractors subject to HEW jurisdiction are subject to the reach of three or more statutory civil rights provisions (e.g. education institutions subject to title VI and title IX and section 504), or to two or more statutory civil rights provisions as well as the nondiscrimination and affirmative action provisions of the Executive Order (e.g. State health agencies subject to title VI, section 504 and Executive Order 11246). This increase in the number of civil rights provisions governing the conduct of a single grantee or contractor is further complicated by the fact that the type of discrimination in employment prohibited by title IX is identical to one of the types of discrimination prohibited by E.O. 11246, and thus, a single institution may be simultaneously responsible for compliance with both authorities. To minimize conflicts caused by these overlaps the Department is developing a coordinated enforcement approach toward reviewing the compliance of a given recipient with all applicable HEW-enforced civil rights provisions. Accordingly, the Secretary believes that it has now become essential to issue a uniform procedural regulation for such enforcement.

The proposed procedures, it should be noted, will not apply to Executive Order 11246 since this Department is not the primary enforcement agency under the Order. The Department of Labor is responsible for development of regulations implementing the Order. It should be noted that almost all contractors subject to HEW jurisdiction under E.O. 11246 are also grantees subject to these procedures, but many grantees subject to these procedures are not contractors subject to HEW jurisdiction under the Executive Order.

In addition to serving the needs of the Department for promoting efficiency and effective enforcement, these proposed procedures will, it is hoped, be helpful to the many grantees of Federal financial assistance administered by the Department in eliminating confusion, overlap and inconsistencies which would assuredly result from adoption of different procedures for effectuating the civil rights requirements of each Federal program in question. A review of the various statutes referred to above provides no substantial reason for differing enforcement procedures and, to the extent that individual programmatic aspects of particular statutes require particularized treatment, special provisions can be developed within the context of a consolidated procedural regulation.

The proposed procedures are similar in many respects to the general procedural provisions of 45 CFR Part 80, the Department's substantive regulation implementing title VI, as well as the current Part 81. There are a number of changes which have been effected to shorten and simplify the presentation. One revision, however, should be noted since it represents an attempt to bring the procedural regulation into line with existing practice and to ensure that the significant increase in the Department's civil rights enforcement responsibilities does not result in either a one-sided or a highly inefficient administrative effort, but rather, in a balanced and organized approach by which the Department will proceed to set its enforcement priorities and under which it will be free to adjust these priorities to meet shifting needs.

The essence of the proposal is to articulate the Department's role in civil rights enforcement in terms of a methodical approach geared toward identifying and eliminating systemic discrimination rather than in terms of a reactive or complaint-oriented approach geared toward securing individual relief for persons claiming discrimination. While individual complaints will continue to be an important factor in scheduling and conducting compliance reviews, the revised procedures are intended as a means of establishing a manageable way for the Office for Civil Rights to handle its overall responsibilities in a manner responsive to the directives of Congress and the President, regardless of what individual complaints may come to the Department's attention.

In this connection, it should be noted that complaints received by the Department over the last few years have not been broadly representative of the spectrum of the Department's civil rights enforcement program, since generally, in any given time period, more complaints involving sex discrimination in higher education academic employment have been received than on any other subject. Departmental enforcement policy must attempt to take into account this skew in complaints received and the factors which contribute to it so as to ensure that whole areas of non-compliance are not ignored merely because few, if any, complaints have been received. This problem is, perhaps, particularly acute in the area of national origin discrimination where potential complainants speak and write English with difficulty.

The need for clarification of departmental roles is derived from several sources: First, as mentioned already, the workload of the Office for Civil Rights has increased appreciably over the years since publication of the current Part 81. In addition to the increase in statutory responsibilities, the high visibility of the Office for Civil Rights in such areas as school desegregation and employment discrimination has resulted in increased public interest and in a concomitant rise in individual complaints of discrimination. Until recently, the Department, operating under its substantive regulations implementing title VI and the Executive Order, has attempted, wherever possible and as quickly as its resources have allowed, to resolve these individual complaints. As statutory responsibilities have increased, however, and as the Office attempted to maintain a rational system of monitoring and of correcting systemic discrimination, it became increasingly difficult to adhere to the assurance in the substantive regulations of prompt investigation of each complaint or other information concerning possible noncompliance.

This difficulty may be illustrated by some figures:

Title VI of the Civil Rights Act of 1964 prohibits discrimination in any federally assisted program or activity on the ground of race, color, or national origin. The bulk of its coverage includes approximately 16,000 public school districts, 2,874 institutions of higher education, and some 30,000 institutions and agencies involved in health and social services programs.

Title IX of the Education Amendments of 1972 generally prohibits discrimination on the basis of sex in federally assisted education programs and activities. It contains several exemptions concerning religiously controlled educational institutions, military schools and others. Its coverage extends primarily to educational institutions but also to organizations and persons which receive federal

assistance in connection with educational programs and activities. Its coverage, therefore, includes approximately 16,000 public school districts, and 2,697 institutions of higher education.

Section 799A of the Public Health Service Act prohibits the Secretary from awarding Federal grants, contracts or other forms of assistance under title VII of PHSA to schools of medicine, osteopathy, dentistry, veterinary medicine, optometry, podiatry and pharmacy, as well as to training centers for allied health personnel unless the Secretary has received a satisfactory assurance that the applicant is not discriminating in admissions to its health-related training programs on the basis of sex. Section 845 of the Act contains similar requirements with respect to schools of nursing. These provisions reach approximately 1,500 institutions.

Section 504 of the Rehabilitation Act of 1973 prohibits discrimination on the basis of handicap in any federally assisted program or activity. Like title VI, it reaches all federally assisted programs and activities and its universe will be identical.

Finally, Executive Order 11246 prohibits discrimination on the basis of race, color, or national origin, religion or sex by government contractors or by contractors performing under federally assisted construction contracts. It is generally administered by the Department of Labor's Office of Federal Contract Compliance, but compliance responsibilities with respect to educational institutions, medical and health-related institutions, social service facilities, certain nonprofit organizations, and state and local public agencies holding Federal government contracts and subcontracts have been delegated to HEW. It applies directly to approximately 863 higher education campuses as well as to some 3,500 construction contractors and nonconstruction contractors outside the field of higher education, but within HEW's jurisdiction.

The so-called "universe" figures given here represent the outer parameters of the civil rights enforcement responsibilities of the Department and of the Office for Civil Rights. Any attempt to monitor compliance as a matter of routine would need to be responsive on this scale. It should, of course, be remembered that in 1964 when the original title VI regulation was issued, and in 1967 when current Part 81 became effective, title VI and the Executive Order were the only major civil rights authorities being administered by the Department. The magnitude of the increase in the Department's responsibilities, therefore, may easily be seen.

In addition to the general increase represented by the "universe" figures, as mentioned earlier, the volume of individual complaints (i.e. those submitted by or on behalf of individuals) also rose. Thus, in 1969, for example, in higher education, five Executive Order and nine title VI complaints were received and resolved, and these two legal authorities were the only two civil rights authorities for which the Department was responsible. In 1974, however, with four major legal authorities, the figures for higher education show the following:

	Executive order	Title IX	Title VI	Public Health Service Act	Total
Complaints received	197	127	118	2	444
Complaints resolved	33	27	30	0	90

At the same time, however, the Office for Civil Rights conducted several hundred compliance reviews, many of which involved institutions or agencies about which individual complaints had been received, and had undertaken a massive compliance effort in response to the original District Court order in *Adams v. Weinberger*, 351 F. Supp. 636 (D.D.C. 1972), 356 F. Supp. 92 (D.D.C. 1973), affirmed with modification, 480 F.2d 1159 (D.C. Cir. 1973), with respect to over 200 school districts and 10 state systems of higher education.

In addition to the civil rights compliance programs discussed above, the workload of the Department and of the Office for Civil Rights includes an increasing role in the annual approval of funds under the Emergency School Assistance Act and an extensive on-going monitoring effort to ensure compliance both with the ESAA requirements and title VI. The size of this task for the present fiscal year is estimated at approximately 1800 desk audits to be performed as pre-grant clearance checks and over 150 on-site compliance reviews to be conducted through the year. While some of the latter reviews might be broadened to allow review of school districts' operations as they are covered by titles VI and IX, the ESAA obligation itself must be fulfilled by the end of each fiscal year (e.g., June 30, 1975) and must be allocated the needed staff and resources.

The second source from which the need for a consolidated and revised procedure is derived is the recently entered Supplemental Order in *Adams v. Weinberger*, supra. Subpart F of that Order states:

> This Court has ruled in this case that HEW has a duty to commence prompt enforcement activity upon all complaints or other information of racial discrimination in violation of Title VI, and that where it appears that a school district is in violation or presumptive violation of Title VI the agency has a duty under Title VI to commence enforcement proceedings by administrative notice of hearing or any other means authorized by law where efforts to obtain voluntary compliance do not succeed within a reasonable period.

The court then establishes a schedule by which HEW is required to act in resolving complaints or taking appropriate enforcement action. In effect, this court order requires the Department to become almost totally complaint-oriented with regard to its enforcement activities under title VI at least in the southern and border states, since the number of complaints subject to the Order now on hand for 1975 is sufficient to occupy existing staff resources responsible for those states full-time in order to ensure compliance with the court's schedule of resolution.

During the 45-day public comment period following publication of this proposed procedural regulation in the FEDERAL REGISTER, the Department intends to seek a modification or a lifting of the restrictions of this portion of the *Adams* order either in the District Court or in the Court of Appeals. If this effort does not result in a change in the order, that order will have a significant impact on all other civil rights activities of the Office for Civil Rights, since it will divert available resources from other compliance activities.

Under the Supplemental decree in *Adams*, and whether or not any other court issues similar orders, the Department would be left unable to fulfill its Congressional mandate which extends beyond the limited scope of the *Adams* order. Investigation, negotiation, and enforcement action concerning isolated incidents of discrimination by a grantee institution or agency can consume as much staff time as monitoring the operations of, for example, some entire school systems. Yet, the result in real compliance obtained as a result of a complaint investigation may be drastically disproportionate to the expenditure of enforcement resources required. Accordingly, the Secretary believes that, in exercise of proper administrative discretion, the re-casting of the Department's role is both justified and advisable.

A final note should be added concerning the nature of these proposed procedures. The Secretary is aware that by describing its civil rights enforcement role in this manner, the Department will be rearticulating its approach. The Secretary believes, however, that a more assertive role in planning and effectuating overall civil rights objectives is necessary to carry out fully the various broadly stated Congressional mandates for which the Department is responsible. As demands on the Office for Civil Rights have increased, several ways of adjusting to the pressures were tried. The budget and staff of the Office for Civil Rights have been substantially increased. Since fiscal 1968, the staff has grown from approximately 330, to approximately 850, in fiscal 1975. Attempts were made, within the context of current regulations to set priorities between the complaints received and routine compliance reviews made. Further, the Department of Labor entered into an agreement with the Equal Employment Opportunity Commission (EEOC) under

which individual complaints of employment discrimination under the Executive Order would be referred by this Department to the EEOC for judicial action. In accordance with this agreement, most complaints of this type have been so referred since March 1972. In addition, since enactment of title IX, when individual complaints of employment discrimination have been received which were not clearly brought under title IX or under the Executive Order, the Department, in an effort to expedite attempts to secure their resolution, has treated those complaints as having arisen under the Executive Order and has referred them to EEOC. Preliminary discussions have been held between the Department and EEOC to develop an agreement under which employment complaints arising solely under title IX could also be referred to EEOC. The referral practice, therefore, could be continued in the context of these proposed procedures.

The Secretary recognizes, however, that the EEOC backlog of cases is substantial. Although aware of this problem, the Secretary feels compelled to propose these new procedures to enhance and maintain the effectiveness of the Department's general civil rights efforts. While all these efforts have been made to improve the effectiveness and impact of the Department's civil rights enforcement program, and while the Department will continue these efforts, none of them singly or in combination promises to overcome the defects inherent in a complaint-dominated regulatory scheme.

SUMMARY OF PROPOSED PROVISIONS

Subpart A, entitled *General*, states the purpose and application of the proposed procedures. As may be seen, the procedures will be applicable both to activities where the Department already has published substantive regulations and to activities where such regulations will be published in the near future. Subpart A also includes definitions of terms used throughout the proposed procedures.

Subpart B, entitled *Compliance Inquiries*, contains provisions which will govern in the administration of the various statutes to which the proposed procedures apply up to the point where enforcement action must be taken to obtain compliance with particular nondiscrimination requirements. Section 81.4(a) requires development and maintenance of data and information by recipients, and § 81.4 (b) requires preservation of such data and information for a period of three years. The three-year period would run from the date of collection of the data or information, except where it relates to grievances and the recipient's treatment of same. In those circumstances, the three-year period would not begin to run until the particular grievance has been resolved or the matter closed. Such a three year period is currently in use by the Department of Labor's Office of Federal Contract Compliance. Section 81.4 (c) requires that the recipient submit to the Director such data and information as the Director may request in connection with the performance of his or her civil rights enforcement duties. Such a request need not be limited to data and information which, under § 81.4(a), the recipient is required to develop and maintain, but reasonable notice of other matters requested will be given to the recipient who will be permitted reasonable time to respond. Section 81.4(d) requires recipients to permit access by the Director to sources of information and to facilities and provides that confidentiality of information will be maintained by the Department except where such information is necessary in formal enforcement proceedings or where otherwise required by law.

Section 81.5 provides that any person or organization may submit information to the Director in writing concerning possible noncompliance with the statutes to which this part applies or their implementing regulations.

Section 81.6 prescribes the treatment to be accorded compliance information received or obtained by the Director. It requires acknowledgement of submissions of information from persons or organizations and an indication as to whether the Department expects to conduct, within the next 12 months, a compliance review which will encompass any or all of the matters concerned in the submission. It also provides that the Director will notify such persons or organizations of government agencies at the Federal, state, and local levels with current legal authority to investigate and act on any or all of the matters raised by the information submitted to the Department. The Director will also inform such persons or organizations of available grievance procedures required of recipients pursuant to some of the statutes to which these proposed procedures apply. Finally, the section provides that the Director will inform the recipient and appropriate State agency, if any, of the general nature of information which has been submitted concerning possible noncompliance of the recipient.

Section 81.7 provides for compliance reviews to be conducted by the Director of the Office for Civil Rights and for written notification of recipients of the results of such reviews.

Section 81.8 requires that the Director promptly notify a recipient in writing if, after a compliance review has been conducted, there is a determination that the recipient is in compliance with the statutes to which this part applies.

Section 81.9 provides for a preliminary finding of noncompliance which will be made known in writing to the recipient together with a description of the possible noncompliance. The recipient may respond within 30 days of its receipt of such a preliminary finding and may offer an explanation or provide further information concerning the matters in the finding. If the Director determines that the explanation or further information offered by the recipient is inadequate or if no such explanation or information is received, the Director will then make a formal determination of noncompliance as soon as is possible under the specific circumstances.

Section 81.10 provides for a formal determination of noncompliance by the Director which will be sent in writing to the recipient together with a description of the reasons therefor.

Section 81.11 provides the mechanism by which the Director will seek to obtain voluntary compliance after making formal determination of noncompliance by a recipient. Generally within 90 days, a recipient must either comply fully or submit a plan satisfactory to the Director by which it will comply fully within a specified time. This section also provides that under unusual circumstances the Director may approve a two step procedure consisting of a commitment submitted by the recipient within 90 days to develop a plan under which it will comply fully within a specified time. The unusual circumstances contemplated by the Secretary in this section may result from combinations of factors such as size, complexities of violations and of relief, and number of recipient agencies involved.

Subpart C, entitled *Enforcement Actions*, includes the provisions governing the conduct of administrative hearings and the initiation of other proceedings authorized by law.

Section 81.12 sets forth the procedure for effecting compliance, including hearings directed to the suspension, termination of, or refusal to award or continue Federal financial assistance, referrals of matters to the Department of Justice for appropriate court action, and actions involving any applicable proceeding under State or local law. Such procedures may be commenced for violations of the nondiscrimination requirements of the statutes to which this Part applies or of their implementing regulations or for failure to furnish assurances of compliance required under applicable Departmental regulations.

Section 81.13 provides for termination of or refusal to award or continue Federal financial assistance. It sets forth limitations on the effective date of termination orders and provides that the scope of any such order will be limited in its effect to the particular program or activity or part thereof in which noncompliance has been found. Specifically, the section states that Federal financial assistance will be subject to a termination order at the close of the appropriate administrative proceeding if it is administered in a discriminatory manner, or if it is so affected by discrimination occurring elsewhere in the recipient's program that the assistance itself may be considered discriminatory.

Section 81.14 sets forth the procedures for conducting administrative hearings. These procedures are commenced by sending a notice of an opportunity for hearing which will advise the applicant for or recipient of Federal financial assistance of the action which the Department proposes to take, the provision or provisions under which that action will be taken and the matters of fact or law asserted as the basis for that action. The

remainder of § 81.14 closely follows current procedures set forth in 45 CFR Part 80 and Part 81 relating to content of notices, waiver of hearing, time and place of hearing, participation as amicus curiae, conformity with other procedural requirements, and consolidated or joint hearings.

Section 81.15 permits the Department to defer consideration of requests or applications for new Federal financial assistance pending the outcome of administrative proceedings. The Department will continue assistance during the pendency of such proceedings where such assistance is due and payable pursuant to an application therefor approved prior to the date of notice of any such deferral. This section is substantively the same as the parallel provision in 45 CFR Part 80.

Section 81.16 concerning decisions and notices is also closely similar to the provisions appearing in 45 CFR Parts 80 and 81. It includes, among other things, provisions concerning decisions by administrative law judges, decisions on exceptions by the Reviewing Authority, review and decision in certain cases by the Secretary, content of orders, and final agency action for purposes of judicial review.

Section 81.17 sets the standards for restoration of eligibility of a recipient which has been subjected to a termination order under this part. It establishes procedures by which such a recipient may request the Director to restore its eligibility and, if the Director refuses such a request, may request a hearing at which to demonstrate that is and will be in compliance, that it has eliminated the effects of past noncompliance, and that it has complied with all terms and conditions of the order of termination issued against it.

Section 81.18 provides for judicial review of final decisions of the Department as provided in the statutes to which this part applies or as is consistent with the Administrative Procedure Act.

Section 81.19 sets out the procedures by which the Director may obtain compliance by other means authorized by law.

Subpart D, entitled *Miscellaneous Provisions*, includes two sections, the substance of both of which appears in current 45 CFR Part 80. The first at §81.-20 prohibits recipients from intimidating, threatening, coercing, or discriminating against any individual because he or she has participated in any manner in an investigation, proceeding or hearing under these proposed procedures or has provided information to the Department concerning any aspect of any such investigation, proceeding, or hearing. The second, at § 81.21, provides that the Department will keep confidential the identity of persons submitting information except to the extent necessary to carry out the purposes of the statutes to which this part applies or their implementing regulations or where otherwise required by law.

Subpart E, entitled *Rules of Practice for Conducting Hearings Under Subpart C of This Part*, includes the technical rules of practice which will govern administrative proceedings. They are not summarized here since the Secretary believes that their content is self-explanatory.

CONCLUSION

In summary, the Secretary firmly believes that the proliferating responsibilities of the Office for Civil Rights and the concomitant rights of recipients and beneficiaries of Federal financial assistance necessitate a uniform and rational procedure for civil rights enforcement. He believes further that the proposed procedures will enable the Office for Civil Rights to make the most effective use of all compliance information requested or made available to it while providing the Office with sufficient flexibility to allocate its resources in a considered and efficient manner. Finally, he believes that the proposed procedures fulfill the need for an orderly and compliance-oriented progression from a preliminary determination of noncompliance to a resolution of the problem or institution of enforcement proceedings, either through the administrative or the judicial route.

Persons or organizations wishing to submit comments, suggestions, or objections pertaining to this regulation may present their views in writing to the Director, Office for Civil Rights, Department of Health, Education, and Welfare, P.O. Box 24079, Washington, D.C. 20024. The comment period will close on July 21, 1975. Comments received in response to this notice will be available for public inspection in Room 3256, 330 Independence Avenue SW., Washington, D.C. 20201, between 9 a.m. and 5:30 p.m., Monday through Friday (except Federal holidays) both before and after the close of the comment period, until the regulation is published in final form.

In consideration of the foregoing, it it proposed to add Part 81 to Title 45 of the Code of Federal Regulations to read as set forth below.

Dated: May 27, 1975.

CASPAR W. WEINBERGER,
Secretary, Department of Health, Education, and Welfare.

PART 81—CONSOLIDATED PROCEDURAL RULES FOR ADMINISTRATION AND ENFORCEMENT OF CERTAIN CIVIL RIGHTS LAWS AND AUTHORITIES

Subpart A—General

Subpart B—Compliance Inquiries

Subpart C—Enforcement Actions

Subpart D—Miscellaneous Provisions

Subpart E—Rules of Practice for Conducting Hearings Under Subpart C of This Part

AUTHORITY: Title IV of the Civil Rights Act of 1964 (42 U.S.C. 2000d), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), secs. 799A and 845 of the Public Health Services Act (42 U.S.C. 295h–9 and 298b–2), sec. 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), sec. 407 of the Alcohol and Drug Abuse Office and Treatment Act of 1972 (42 U.S.C. 1173), sec. 321 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. 4587).

Subpart A—General

§ 81.1 Purpose.

The purpose of this subpart is to establish uniform procedures for enforcing nondiscrimination requirements under various statutes administered by the Department.

§ 81.2 Applicability.

The procedures established by this subpart apply to the nondiscrimination requirements of title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) as implemented at 45 CFR Part 80; title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) as implemented at 45 CFR Part 86; sections 799A and 845 of the Public Health Service Act (42 U.S.C. 295h–9 and 298b–2); section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); section 407 of the Alcohol and Drug Abuse Office and Treatment Act of 1972 (42 U.S.C. 1173); and section 321 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4587).

§ 81.3 Definitions.

As used in this part the term—

(a) "Department" means the Department of Health, Education, and Welfare.

(b) "Secretary" means the Secretary of Health, Education, and Welfare.

(c) "Director" means the Director of the Office for Civil Rights of the Department.

(d) "Reviewing Authority" means the component of the Department delegated authority by the Secretary to appoint and to review the decisions of administrative law judges in cases arising under this part.

(e) "Administrative Law Judge" means a person appointed by the Reviewing Authority to preside over a hearing held under this part.

(f) "Federal financial assistance" means any assistance authorized or extended under a law administered by the Department by means of a grant, loan, contract, or other arrangement (except to the extent that contracts of insurance or guaranty are exempt from coverage under title VI of the Civil Rights Act of 1964 and title IX of the Education Amendments of 1972 or other nondiscrimination statute), including:

(1) Funds made available for the acquisition, construction, renovation, restoration, or repair of a building or a facility or any portion thereof;

(2) Funds made available for scholarships, loans, grants, or wages, or other funds extended for payment to or on behalf of students or other participants in a program or activity covered by any statute to which this part applies;

(3) Use of Federal real or personal property or any interest therein, including surplus property, and the proceeds of the sale or transfer of such property if the Federal share of the fair market value of the property is not, upon such sale or transfer, properly accounted for to the Federal Government;

(4) Federal property or any interest therein which is sold or donated to a person, institution, or other organization at nominal consideration, or at consideration reduced for the purpose of assisting the person, institution or other organization or in recognition of public interest to be served thereby, or by permission given to use such Federal property or any interest therein without consideration.

(g) "Recipient" means any State or political subdivision thereof, or any instrumentality of a State or poliitcal subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or through another recipient.

(h) "Applicant" means any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution or organization, or other entity, or any person having pending with the Department an application, request, or plan required to be approved by a Department official, as a condition to becoming a recipient. Unless otherwise stated, rights and obligations accorded to or imposed on recipients pursuant to this part will be deemed accorded to or imposed on applicants.

Subpart B—Compliance Inquiries

§ 81.4 Compliance information.

(a) *Development and maintenance of information.* Recipients shall develop and maintain data and information concerning their programs or activities which are subject to statutes to which this part applies. Such data and information shall relate to:

(1) Application, admission and assignment of students, members or other participants;

(2) Recruitment of students, faculty, staff, and other participants;

(3) Financial aid administered or provided by the recipient;

(4) Recruitment, selection, assignment, promotion, salary, training, demotion and separation of employees;

(5) Grievances and effectiveness of grievance procedures;

(6) Disciplinary rules and application thereof; and

(7) Such other matters as the Director may from time to time designate.

(b) Recipients shall preserve the data and information developed and maintained pursuant to paragraph (a) of this section together with appropriate supporting materials for a period of three years provided that the three year period in the case of paragraph (a)(5) of this section will run from the time a particular grievance has been resolved or closed.

(c) *Provision of information to the Director.* At the request of the Director, recipients shall prepare and furnish such data and information as the Director may request in connection with the performance of the duties of the Director under this part.

(d) *Access to sources of information.* Each recipient shall permit access by the Director during normal business hours to such of its books, records, accounts, other documents, and to its facilities, and shall permit the Director to make copies of any such written information as may be pertinent to ascertain compliance with this part. Asserted considerations of privacy or confidentiality may not operate to bar the Department from evaluating or seeking to enforce compliance with this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement will not be disclosed by the Department except where necessary in formal enforcement proceedings or where otherwise required by law.

§ 81.5 Submission of information.

Any person or organization wishing to provide information concerning possible noncompliance with statutes to which this part applies or with their implementing regulations may submit such information to the Director in writing.

§ 81.6 Treatment of compliance information.

(a) *General.* The Director will consider all compliance information, regardless of whether it is received through submissions from individuals or organizations outside the Department, through reports submitted to the Department by recipients, or through onsite inspection of recipients' programs or activities by the Department, in setting priorities for the Department's compliance program under this part.

(b) *Acknowledgment of submissions of information.* The Director will acknowledge each submission of information and will notify the person or organization submitting such information as to whether the Department expects to conduct a compliance review which will encompass any or all of the matters concerned in the submission within the next 12 months.

(c) *Notification of sources of relief.* Upon receipt of each submission of information concerning possible noncompliance by a recipient, the Director will:

(1) Notify the person or organization submitting information of those governmental agencies at the Federal, state and local levels known to have current legal authority (i) to conduct an investigation of the matter or matters raised in such submission of information, and (ii) to take legal action designed to compel a recipient to provide a remedy to any person determined by such an investigation to have been discriminated against;

(2) Inform such an individual or organization of any grievance procedures or mechanisms which are required to be available pursuant to statutes to which this part applies and applicable implementing regulations; and

(3) Inform the recipient about whom information as to possible noncompliance

has been submitted and the appropriate State agency, if any, of the general nature of that information.

§ 81.7 Compliance reviews.

(a) *Conduct of reviews.* The Director will periodically review the practices and policies of recipients to determine whether they are complying with the statutes to which this part applies and their implementing regulations. Using all data and information available to the Department in reports submitted by recipients, through on-site inspection of recipients' programs or activities, or through submissions from individuals or organizations outside the Department, and taking into account priorities and available resources, the Director will decide where and on what schedule compliance reviews will be made.

(b) *Notification of results of reviews.* Upon completion of a compliance review, the Director will notify the recipient, in writing, of the results of the review.

§ 81.8 Determination of compliance.

Whenever the Director determines as the result of a compliance review conducted pursuant to § 81.7 of this part or as the result of any other review of available data and information, that the recipient reviewed is in compliance with the statutes to which this part applies, the Director will promptly so notify the recipient in writing.

§ 81.9 Preliminary finding of noncompliance.

(a) *Finding and notification.* Whenever the Director, on the basis of a compliance review conducted pursuant to § 81.7 of this part, or on the basis of any other available data and information, finds evidence of possible noncompliance, or otherwise determines that possible noncompliance exists, the Director will provide written notification to the recipient of this preliminary finding together with a description of the possible noncompliance.

(b) *Explanation of findings.* The Director will provide the recipient an opportunity to submit within 30 days an explanation or further information concerning the matters described in the notification, or to make such other response to the notification as the recipient considers appropriate.

§ 81.10 Determination of noncompliance.

Whenever the Director determines that a recipient has failed to comply with the statutes to which this part applies and their implementing regulations, the Director will notify the recipient of this determination together with a statement of the reasons therefor.

§ 81.11 Voluntary compliance.

(a) *General.* Upon receipt of notification of a determination of noncompliance made pursuant to § 81.10 of this part, the recipient shall, within 90 days:

(1) Comply fully with the statutes to which this part applies and with their implementing regulations and eliminate the effects of past noncompliance; or

(2) Submit a plan satisfactory to the Director by which within a time therein specified, it will comply fully with the statutes to which this part applies and with their implementing regulations and will eliminate the effects of past noncompliance.

(b) *Unusual circumstances.* Upon receipt of notification of a determination of noncompliance made pursuant to § 81.10 of this part, and with the approval of the Director based on the existence of unusual circumstances, the recipient shall, within 90 days, submit to the Director a commitment that within a specified time it will take appropriate action under paragraph (a) of this section.

(c) *Failure to participate.* Nothing in this section shall be interpreted to preclude the Director from determining at any time that efforts to secure voluntary compliance have failed or will be unsuccessful because of failure of the recipient to participate or agree to participate in such efforts.

Subpart C—Enforcement Actions

§ 81.12 Procedure for effecting compliance.

(a) *General.* If the Director determines that a recipient has failed to comply with statutes to which this part applies, and if the noncompliance cannot be corrected by informal means as set forth in § 81.11 of this part, compliance by the recipient may be effected by the suspension or termination of or refusal to award or continue Federal financial assistance in accordance with this part, or by any other means authorized by law. Such other means of effecting compliance may include, but are not limited to:

(1) Referral to the Department of Justice with a recommendation that appropriate proceedings be brought to enforce any rights of the United States under any law of the United States, or any assurance or other contractual undertaking; and

(2) Action involving any applicable proceeding under State or local law.

(b) *Noncompliance with assurance requirements.* If an applicant or recipient fails or refuses to furnish an assurance of compliance required under Departmental regulations and their implementing statutes to which this part applies, or otherwise fails or refuses to comply with a requirement imposed by or pursuant to those statutes, and efforts to achieve compliance pursuant to § 81.11 of this part have failed, Federal financial assistance may be terminated and refused in accordance with the procedures set out in this part, or the Director may seek to effect compliance by other means authorized by law pursuant to paragraph (a) of this section.

§ 81.13 Termination of or refusal to grant or to continue Federal financial assistance.

(a) *Effective date of order.* Where required under statutes to which this part applies or their implementing regulations, no order suspending, terminating or refusing to award or continue Federal financial assistance will become effective until:

(1) The Director has advised the applicant or recipient of its failure to comply and has determined that compliance cannot be secured by voluntary means;

(2) There has been a finding on the record, after opportunity for hearing, of a failure by the applicant or recipient to comply with a requirement imposed by or pursuant to this part, the statutes to which this part applies, and their implementing regulations; and

(3) Thirty days have expired after the Secretary has filed with the committee of the House and the committee of the Senate having legislative jurisdiction over the program involved, a full written report of the circumstances and the grounds for such action.

(b) *General scope of order.* Any action to suspend or terminate or to refuse to award or continue Federal financial assistance shall be limited to the particular political entity, or part thereof, or other applicant or recipient as to whom such a finding has been made and shall be limited in its effect to the particular program or activity or part thereof in which such noncompliance has been so found.

(c) *Application.* Where Federal financial assistance to a recipient is designated for a particular purpose or range of purposes, it will be subject to an order terminating and refusing to award or continue Federal financial assistance pursuant to this part if:

(1) The assistance is administered in a discriminatory manner; or

(2) The assistance is so affected by discrimination occurring elsewhere in the recipient's program or activity that the assistance itself may be considered discriminatory.

§ 81.14 Hearings.

(a) *Opportunity for hearing.* Whenever an opportunity for a hearing is required under this part, reasonable written notice will be given to each affected applicant or recipient. The notice will advise such applicant or recipient of the action proposed to be taken, the specific provision or provisions under which the proposed action against it is to be taken, and the matters of fact or law asserted as the basis for this action.

(b) *Content of notice.* A notice under paragraph (a) of this section will:

(1) Fix a date not less than 20 days after the date of such notice within which the applicant or recipient may request the Director in writing that the matter concerned in the notice be scheduled for hearing; or

(2) Advise such applicant or recipient that the matter concerned in the notice has been set down for hearing at a stated place and time which will be subject to change at the request of the applicant or recipient upon a showing of good cause.

(c) *Waiver of hearing.* An applicant or recipient may waive a hearing and, instead, submit written information and argument for the record. The failure of

an applicant or recipient to request a hearing or to make an appearance at a hearing for which a date has been set without prior notification to the administrative law judge or the Reviewing Authority will be deemed to be a waiver of the right to a hearing under the statutes and regulations cited in the notice of opportunity for hearing and under this part.

(d) *Time and place of hearing.* Hearings will be held before an administrative law judge. Hearings will be held at the offices of the Department in Washington, D.C., at a time fixed by the Director unless the administrative law judge determines that the convenience of the applicant or recipient or of the Department requires that another place be selected.

(e) *Public notice of enforcement actions.* The Director will publish monthly in the FEDERAL REGISTER notice of the following actions:

(1) All administrative hearings completed during the prior month;

(2) All administrative hearings scheduled for the coming month (subject to change without further notice);

(3) All exceptions filed with the Reviewing Authority;

(4) All Reviewing Authority decisions on fund termination proceedings;

(5) All decisions by the Secretary to review decisions of the Reviewing Authority; and

(6) All referrals of matters to the Department of Justice or other actions taken to secure compliance with the statutes to which this part applies and their implementing regulations by other means authorized by law as provided in § 81.12 of this part.

(f) *Participation as amicus curiae.* Any interested person or organization may petition the administrative law judge for leave to participate as amicus curiae by giving testimony concerning pertinent facts and/or by filing briefs in a hearing held pursuant to this part. Such petition shall be submitted no more than 20 days after the date of the notice prescribed by § 81.12 of this part.

(g) *Procedures.* The hearing, decision, and any administrative review thereof will be conducted in conformity with 5 U.S.C. 554–557 and in accordance with Subpart E of this part and any other rules which the Director may prescribe.

(h) *Consolidated or joint hearing.* In cases in which the same or related facts are asserted to constitute noncompliance with two or more statutes to which this part applies, or their implementing regulations, or noncompliance with the regulations of this Department and of one or more other Federal departments or agencies issued under any of the authorities to which this part applies, the Director may, by agreement with such other departments or agencies, provide for the conduct of consolidated or joint hearings. Final decisions in such cases, insofar as this regulation is concerned, shall be made in accordance with this section and with Subpart E of this part.

§ 81.15 Deferral of consideration of applications or requests for new Federal financial assistance pending completion of an administrative proceeding.

The Department may defer action on applications or requests for new Federal financial assistance or for substantial increases in continuing forms of Federal financial assistance during the pendency of the administrative proceedings under this part, except that the Department will continue assistance during the pendency of such proceedings where such assistance is due and payable pursuant to an application therefor approved prior to the date of notice of any such deferral.

§ 81.16 Decisions and notices.

(a) *Decisions by administrative law judges.* After a hearing is completed, the administrative law judge will make an initial decision, and a copy of such initial decision or certification will be mailed to the applicant or recipient as well as to any amicus curiae.

(b) *Exceptions.* Within 20 days after issuance of the initial decision pursuant to this section, the applicant or recipient or the Department may file with the Reviewing Authority exceptions to the initial decision, together with the reasons therefor. Responses to such exceptions, if any, must be filed with the Reviewing Authority within 10 days of the filing of the first exceptions.

(c) *Oral argument on review.* If an applicant, recipient, or the Department desires to argue a case orally on exceptions or replies to exceptions to an initial decision, that party shall make such request in writing. The Reviewing Authority may grant or deny such requests in its discretion. If granted, it will serve notice of oral argument on all parties. The notice will set forth the order of presentation, the amount of time allotted, and the time and place for argument.

(1) The names of persons who will argue should be filed with the Department hearing clerk not later than 7 days before the date set for oral argument.

(2) The purpose of oral argument is to emphasize and clarify the written argument in the briefs.

(3) Pamphlets, charts, and other written material may be presented at oral argument only if such material is limited to facts already in the record and is served on all parties and filed with the Civil Rights hearing clerk at least 7 days before the argument.

(d) *Decisions on review.* Upon the receipt of such exceptions and responses, the Reviewing Authority will review the initial decision, exceptions, and responses and issue its own decision, including the reasons therefor. In the absence of exceptions, the initial decision will constitute the final decision of the Department.

(e) *Incapacity of administrative law judge.* Whenever, after being designated as the hearing officer for a particular matter, an administrative law judge becomes unable to complete his or her duties specified under this part, jurisdiction as to the matter in question will revert to the Reviewing Authority which may complete the administrative procedure under this part either by designating a new administrative law judge, or by taking other such actions as it deems appropriate under the circumstances.

(f) *Decisions on record without a hearing.* Whenever a hearing is waived pursuant to § 81.14(c) of this part, the Reviewing Authority will make its final decision on the record or refer the matter to an administrative law judge for an initial decision to be made on the record. A copy of such decision will be provided to the applicant or recipient and to any amicus curiae.

(g) *Rulings required.* Each decision of an administrative law judge or of the Reviewing Authority will set forth a ruling on each finding, conclusion, or exception presented, and shall identify the requirement or requirements imposed by or pursuant to the statutes to which this part applies with which it is found that the applicant or recipient has failed to comply.

(h) *Review in certain cases by the Secretary.* Within 30 days after issuance of the final decision by the Reviewing Authority, a recipient or applicant or the Department may request the Secretary to review such decision. Such review will be granted only where the Secretary determines there are special and important reasons therefor. The Secretary may also review the final decision of the Reviewing Authority upon his or her own motion. The Secretary's decision to undertake or not to undertake such review whether at the request of a party or on his or her own motion will be communicated in writing after the issuance of the Reviewing Authority's decision, to each party, and any amicus curiae. Failure of an applicant or recipient to file an exception with the Reviewing Authority or to request review under this paragraph will not be deemed a failure to exhaust administrative remedies for the purpose of obtaining judicial review.

(i) *Final agency action for purposes of judicial review.*

(1) A decision under this section will become the final decision of the Department and will constitute final agency action within the meaning of section 704 of title 5 of the United States Code in the following manner:

(i) A decision by an administrative law judge pursuant to this section will become final on the 21st day after such decision is made, unless prior to such day review by the Reviewing Authority has been requested;

(ii) A decision by the Reviewing Authority pursuant to this section will become final on the 31st day following its issuance unless review by the Secretary is requested prior to such day under this section; and

(iii) A decision of the Secretary under this section will become final on the day following its issuance.

(2) Whenever required by or pursuant to a statute to which this part applies,

a decision to terminate or to refuse to award or continue Federal financial assistance, which would otherwise constitute the final decision of the Department and final agency action pursuant to paragraph (h) of this section, shall not constitute such action until the Secretary transmits it as such to the appropriate Congressional committees with a report of his action as described in § 81.13(a)(3) of this part.

(j) *Content of decision.* The final decision will include an order for suspension or termination of, or refusal to award or continue, in whole or in part, Federal financial assistance to which this part applies, and may contain such terms, conditions, and other provisions as are consistent with and which will effectuate the purposes of the statutes to which this part applies.

(k) An order issued pursuant to this part terminating and refusing to award or continue Federal financial assistance will remain in effect unless and until the recipient corrects its noncompliance and satisfies the Director that it will fully comply with the statutes and regulations as to which it has been found in noncompliance.

§ 81.17 Post-termination proceedings.

(a) An applicant or recipient subject to an order issued under § 81.16(i) of this part shall be restored to full eligibility to receive Federal financial assistance if it satisfies the terms and conditions of that order for such eligibility, or it corrects its noncompliance and the effects of past noncompliance and satisfies the Director that it will fully comply with the statutes and regulations as to which its noncompliance was found.

(b) Any applicant or recipient subject to an order entered pursuant to § 81.16(i) of this part may at any time following the effective date of the order request the Director to restore its eligibility to receive Federal financial assistance. Such a request shall be supported by information showing that the applicant or recipient has met the requirements of paragraph (a) of this section. If the Director determines that those requirements have been satisfied, he or she will restore such eligibility.

(c) If the Director denies any such request, the applicant or recipient may submit a written request for a hearing to be conducted pursuant to this part, specifying why it believes the Director's decision refusing renewal of eligibility to have been in error. The recipient will be entitled to a hearing, with a decision on the record, in accordance with rules of procedure contained in this part and such further rules as the Director prescribes. The applicant or recipient will be restored to such eligibility if as a result of such a hearing the administrative law judge determines that the applicant or recipient has satisfied the requirements of paragraph (a) of this section.

(d) In the event that a hearing is requested pursuant to paragraph (c) of this section, the hearing procedures established by this part shall be applicable to the proceedings, except as otherwise provided in this section.

(e) The pendency of any proceeding under this section shall not lift or stay the sanctions imposed by the order issued under § 81.16(i) of this part.

§ 81.18 Judicial review.

Final decisions of the Department as defined in § 81.16(h) of this part are subject to judicial review as provided in the statutes to which this part applies or as is consistent with Chapter 5 of title 5, United States Code.

§ 81.19 Other means authorized by law.

(a) No action to effect compliance by any other means authorized by law as provided in § 81.12 of this part will be taken by the Director until: (1) The Director determines that compliance cannot be secured by voluntary means pursuant to § 81.11 of this part, (2) the recipient has been notified of its failure to comply and of the action to be taken to effect compliance, and (3) the expiration of at least 10 days from the mailing of such notice to the recipient. During this period of at least 10 days, the recipient will be afforded an additional opportunity to comply with this part and to take such corrective action as may be appropriate.

(b) Other means authorized by law include referral of a matter to the Department of Justice with a recommendation that appropriate judicial action be taken to enforce the statutes to which this part applies and their implementing regulations, as well as any applicable assurances of compliance, and other actions determined by the Director to be in the interests of justice and consistent with the statutes to which this part applies and their implementing regulations.

(c) Nothing in this section shall preclude the Director from taking preliminary action to notify other agencies, including the Department of Justice, of the Department's intention to take action under this section and to provide such information as may be necessary to such other agencies to enable them to take any appropriate steps to assist in such enforcement after the expiration of the 10 day waiting period prescribed under paragraph (a) of this section.

Subpart D—Miscellaneous Provisions

§ 81.20 Intimidatory or retaliatory acts prohibited.

Each recipient shall permit the Director to interview any of its students or employees without a representative of such recipent being present. No recipient shall intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any rights or privileges secured by the statutes to which this part applies or by this part, or because he or she has testified, assisted or participated in any manner in an investigation, proceeding or hearing.

§ 81.21 Identity of persons submitting information.

The identity of persons submitting information will be kept confidential by the Department except to the extent necessary to carry out the purposes of the statutes to which this part applies or their implementing regulations, including the conduct of any investigation, hearing, or judicial proceeding arising thereunder, or where otherwise required by law.

Subpart E—Rules of Practice for Conducting Hearings Under Subpart C of This Part

§ 81.30 Records to be public.

All pleadings, correspondence, exhibits, transcripts of testimony, exceptions, briefs, decisions, and other documents filed in the docket in any proceeding may be inspected and copies in the office of the Civil Rights Hearing Clerk. Inquiries may be made at the Central Information Center, Department of Health, Education, and Welfare, 330 Independence Avenue SW., Washington, D.C. 20201.

§ 81.31 Use of gender and number.

As used in this part, words importing the singular number may extend and be applied to several persons or things, and vice versa. Words importing the masculine gender may be applied to females or organizations.

§ 81.32 Suspension of rules.

Upon notice to all parties, the Reviewing Authority or the presiding officer, with respect to matters pending before them, may modify or waive any rule in this part upon determination that no party will be unduly prejudiced and the ends of justice will thereby be served.

§ 81.33 Parties.

(a) The term "party" shall include an applicant or recipient to whom a notice of hearing or opportunity for hearing has been mailed naming him as respondent.

(b) The General Counsel of the Department of Health, Education, and Welfare shall be deemed a party to all proceedings.

(c) A person or organization which has been granted permission to participate in a proceeding pursuant to this part as an amicus curiae shall not be deemed a party to such proceeding. An amicus curiae may:

(1) Submit a statement of position to the presiding officer prior to the beginning of a hearing, and shall serve a copy on each party;

(2) Submit a brief on each occasion a decision is to be made, or a prior decision is subject to review, which shall be filed and served on each party within the time limits applicable to the party whose position the amicus curiae deems himself to support or, if he does not deem himself to support the position of any party, within the longest time limit applicable to any party at that particular stage of the proceedings;

(3) With the permission of the presiding officer, offer material which the presiding officer determines will assist materially in elucidating factual matters at issue between the parties and which will not expand the issues.

(d) A person submitting information to the Director concerning the possible noncompliance of an applicant or recipient pursuant to § 81.5 of this part is not a party to the proceedings governed by this part, but may petition to become an amicus curiae.

§ 81.34 Appearance.

A party may appear in person or by counsel and participate fully in any proceeding. A State agency or a corporation may appear by any of its officers or by any employee it authorizes to appear on its behalf. Counsel must be members in good standing of the bar of a State, Territory, or possession of the United States or of the District of Columbia or the Commonwealth of Puerto Rico.

§ 81.35 Authority for representation.

Any individual acting in a representative capacity in any proceeding may be required to show his authority to act in such capacity.

§ 81.36 Exclusion from hearing for misconduct.

Disrespectful, disorderly, or contumacious language contemptuous conduct, refusal to comply with directions, or continued use of dilatory tactics by any person at any hearing before a presiding officer shall constitute grounds for immediate exclusion of such person from the hearing by the presiding officer.

§ 81.37 Form of documents to be filed.

Documents to be filed under the rules in this part shall be dated, the original signed in ink, shall show the docket description and title of the proceeding, and shall show the title, if any, and address of the signatory. Copies need not be signed but the name of the person signing the original shall be reproduced. Documents shall be legible and shall not be more than 8½ inches wide and 12 inches long. All documents filed should be accompanied by two copies.

§ 81.38 Signature of documents.

The signature of a party, authorized officer, employee or attorney constitutes a certificate that he has read the document, that to the best of his knowledge, information, and belief there is good ground to support it, and that it is not interposed for delay. If a document is not signed or is signed with intent to defeat the purpose of this part, it may be stricken as sham and false and the proceeding may proceed as though the document had not been filed. Similar action may be taken if scandalous or indecent matter is inserted.

§ 81.39 Filing and service.

All notices by a Department official, and all written motions, requests, petitions, memoranda, pleadings, exceptions, briefs, decisions, and correspondence to a Department official from a party, or vice versa, relating to a proceeding after its commencement shall be filed and served on all parties. Parties shall supply the original and two copies of documents submitted for filing. Filings shall be made with the Civil Rights hearing clerk at the address stated in the notice of hearing or notice of opportunity for hearing, during regular business hours. Regular business hours are every Monday through Friday (legal holidays in the District of Columbia excepted) from 9 a.m. to 5:30 p.m., eastern standard or daylight saving time, whichever is effective in the District of Columbia at the time. Originals only of exhibits and transcripts of testimony need be filed.

§ 81.40 Service—how made.

Service shall be made by personal delivery of one copy to each person to be served or by mailing by first-class mail, properly addressed with postage prepaid. When a party or amicus has appeared by attorney or other repersentative, service upon such attorney or representative will be deemed service upon the party or amicus. Documents served by mail preferably should be mailed in sufficient time to reach the addressee by the date on which the original is due to be filed, and should be air mailed if the addressee is more than 300 miles distant.

§ 81.41 Date of service.

The date of service shall be the day when the matter is deposited in the U.S. mail or is delivered in person, except that the date of service of the initial notice of hearing or opportunity for hearing shall be the date of its delivery, or of its attempted delivery if refused.

§ 81.42 Certificate of service.

The original of every document filed and required to be served upon parties to a proceeding shall be endorsed with a certificate of service signed by the party making service or by his attorney or representative, stating that such service has been made, the date of service, and the manner of service, whether by mail or personal delivery.

§ 81.43 Computation of time.

In computing any period of time under the rules in this part or in an order issued hereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed in the District of Columbia, in which event it includes the next following business day. When the period of time prescribed or allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays shall be excluded from the computation.

§ 81.44 Extension of time or postponement.

Requests for extension of time should be served on all parties and should set forth the reasons for the application. Applications may be granted upon a showing of good cause by the applicant. From the designation of a presiding officer until the issuance of his decision such requests should be addressed to him. Answers to such requests are permitted, if made promptly.

§ 81.45 Reduction of time to file documents.

For good cause, the Reviewing Authority or the presiding officer, with respect to matters pending before them, may reduce any time limit prescribed by the rules in this part, except as provided by law or elsewhere in this part.

§ 81.46 Notice of hearing or opportunity for hearing.

Proceedings are commenced by mailing a notice of hearing or opportunity for hearing to an affected applicant or recipient, pursuant to § 81.40 of this part.

§ 81.47 Answer to notice.

The respondent, applicant or recipient may file an answer to the notice within 20 days after service thereof. Answers shall admit or deny specifically and in detail each allegation of the notice, unless the respondent party is without knowledge, in which case his answer should so state, and the statement will be deemed a denial. Allegations of fact in the notice not denied or controverted by answer shall be deemed admitted. Matters alleged as affirmative defenses shall be separately stated and numbered. Failure of the respondent to file an answer within the 20-day period following service of the notice may be deemed an admission of all matters of fact recited in the notice.

§ 81.48 Amendment of notice or answer.

The General Counsel may amend the notice of hearing or opportunity for hearing once as a matter of course before an answer thereto is served, and each respondent may amend his answer once as a matter of course not later than 10 days before the date fixed for hearing but in no event later than 20 days from the date of service of his original answer. Otherwise a notice or answer may be amended only by leave of the presiding officer. A respondent shall file his answer to an amended notice within the time remaining for filing the answer to the original notice or within 10 days after service of the amended notice, whichever period may be the longer, unless the presiding officer otherwise orders.

§ 81.49 Request for hearing.

Within 20 days after service of a notice of opportunity for hearing which does not fix a date for hearing the respondent, either in his answer or in a separate document, may request a hearing. Failure of the respondent to request a hearing shall be deemed a waiver of the right to a hearing and to constitute his consent to the making of a decision on the basis of such information as is available.

§ 81.50 Consolidation.

The presiding officer may provide for proceedings in the Department to be joined or consolidated for hearing with proceedings in other Federal departments or agencies, by agreement with such other departments or agencies and pursuant to § 81.14(h). All parties to any proceeding consolidated subsequently to service of the notice of hearing or opportunity for hearing shall be promptly served with notice of such consolidation.

§ 81.51 Motions.

Motions and petitions shall state the relief sought, the authority relied upon, and the facts alleged. If made before or after the hearing, these matters shall be

in writing. If made at the hearing, they may be stated orally; but the presiding officer may require that they be reduced to writing and filed and served on all parties in the same manner as a formal motion. Motions, answers, and replies shall be addressed to the presiding officer, if the case is pending before him. A repetitious motion will not be entertained.

§ 81.52 Responses to motions and petitions.

Within 8 days after a written motion or petition is served, or such other period as the Reviewing Authority or the presiding officer may fix, any party may file a response thereto. An immediate oral response may be made to an oral motion.

§ 81.53 Disposition of motions and petitions.

The Reviewing Authority or the presiding officer may not sustain or grant a written motion or petition prior to expiration of the time for filing responses thereto, but may overrule or deny such motion or petition without awaiting response: *Provided however,* That prehearing conferences, hearings and decisions need not be delayed pending disposition of motions or petitions. Oral motions and petitions may be ruled on immediately. Motions and petitions submitted to the Reviewing Authority or the presiding officer, respectively, and not disposed of in separate rulings or in their respective decisions will be deemed denied. Oral arguments shall not be held on written motions or petitions unless the presiding officer in his discretion expressly so orders.

§ 81.54 Who presides.

An administrative law judge shall preside over the taking of evidence in any hearing to which these rules of procedure apply.

§ 81.55 Designation of administrative law judge as presiding officer.

The designation of the administrative law judge as presiding officer shall be in writing. A copy of such order shall be served on all parties. After service of an order designating an administrative law judge to preside, and until such judge makes his decision, motions and petitions shall be submitted to him.

§ 81.56 Authority of presiding officer.

The presiding officer shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. He shall have all powers necessary to these ends, including (but not limited to) the power to:

(a) Arrange and issue notice of the date, time, and place of hearings, or, upon due notice to the parties, to change the date, time, and place of hearings previously set.

(b) Hold conferences to settle, simplify, or fix the issues in a proceeding, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(c) Require parties and amici curiae to state their position with respect to the various issues in the proceeding.

(d) Administer oaths and affirmations.

(e) Rule on motions, and other procedural items on matters pending before him.

(f) Regulate the course of the hearing and conduct of counsel therein.

(g) Examine witnesses and direct witnesses to testify.

(h) Receive, rule on, exclude or limit evidence.

(i) Fix the time for filing motions, petitions, briefs, or other items in matters pending before him.

(j) Issue initial or recommended decisions.

(k) Take any action authorized by the rules in this Part or in conformance with the provisions of 5 U.S.C. 551–559 (the Administrative Procedure Act).

§ 81.57 Statement of position and trial briefs.

The presiding officer may require parties and amici curiae to file written statements of position prior to the beginning of a hearing. The presiding officer may also require the parties to submit trial briefs.

§ 81.58 Evidentiary purpose.

(a) The hearing is directed to receiving factual evidence and expert opinion testimony related to the issues in the proceeding. Argument will not be received in evidence; rather it should be presented in statements, memoranda, or briefs, as determined by the presiding officer. Brief opening statements, which shall be limited to statement of the party's position and what he intends to prove, may be made at hearings.

(b) Hearings for the reception of evidence will be held only in cases where issues of fact must be resolved in order to determine whether the respondent has failed to comply with one or more applicable requirements of the statutes to which this part applies or their implementing regulations or this part. In any case where it appears from the respondent's answer to the notice of hearing or opportunity for hearing, from his failure timely to answer, or from his admissions or stipulations in the record, that there are no matters of material fact in dispute, the Reviewing Authority or presiding officer may enter an order so finding, vacating the hearing date if one has been set, and fixing the time for filing briefs under § 81.74. Thereafter the proceedings shall go to conclusion in accordance with this part. The presiding officer may allow an appeal from such order in accordance with § 81.71.

§ 81.59 Testimony.

Testimony shall be given orally under oath or affirmation by witnesses at the hearing; but the presiding officer, in his discretion, may require or permit that the direct testimony of any witness be prepared in writing and served on all parties in advance of the hearing. Such testimony may be adopted by the witness at the hearing, and filed as part of the record thereof. Unless authorized by the presiding officer, witnesses will not be permitted to read prepared testimony into the record. Except as provided in §§ 81.60 and 81.61, witnesses shall be available at the hearing for cross-examination.

§ 81.60 Exhibits.

Proposed exhibits shall be exchanged at the prehearing conference, or otherwise prior to the hearing if the presiding officer so requires. Proposed exhibits not so exchanged may be denied admission as evidence. The authenticity of all proposed exhibits exchanged prior to hearing will be deemed admitted unless written objection thereto is filed prior to the hearing or unless good cause is shown at the hearing for failure to file such written objection.

§ 81.61 Affidavits.

An affidavit is not inadmissible as such. Unless the presiding officer fixes other time periods affidavits shall be filed and served on the parties not later than 15 days prior to the hearing; and not less than 7 days prior to hearing a party may file and serve written objection to any affidavit on the ground that he believes it necessary to test the truth of assertions therein at hearing. In such event the assertions objected to will not be received in evidence unless the affiant is made available for cross-examination, or the presiding officer determines that cross-examination is not necessary for the full and true disclosure of facts referred to in such assertions. Notwithstanding any objection, however, affidavits may be considered in the case of any respondent who waives a hearing.

§ 81.62 Depositions.

Upon such terms as may be just, for the convenience of the parties or of the Department, the presiding officer may authorize or direct the testimony of any witness to be taken by deposition.

§ 81.63 Admissions as to facts and documents.

Not later than 15 days prior to the scheduled date of the hearing except for good cause shown, or prior to such earlier date as the presiding officer may order, any party may serve upon an opposing party a written request for the admission of the genuineness and authenticity of any relevant documents described in and exhibited with the request, or for the admission of the truth or any relevant matters of fact stated in the request. Each of the matters of which an admission is requested shall be deemed admitted, unless within a period designated in the request (not less than 10 days after service thereof, or within such further time as the presiding officer or the Reviewing Authority if no presiding officer has yet been designated may allow upon motion and notice) the party to whom the request is directed serves upon the requesting party a sworn statement either denying specifically the matters of which an admission is requested or setting forth in de-

tail the reasons why he cannot truthfully either admit or deny such matters. Copies of requests for admission and answers thereto shall be served on all parties. Any admission made by a party to such request is only for the purposes of the pending proceeding, or any proceeding or action instituted for the enforcement of any order entered therein, and shall not constitute an admission by him for any other purpose or be used against him in any other proceeding or action.

§ 81.64 Evidence.

Irrelevant, immaterial, unreliable, and unduly repetitious evidence will be excluded.

§ 81.65 Cross-examination.

A witness may be cross-examined on any matter material to the proceeding without regard to the scope of his direct examination.

§ 81.66 Unsponsored written material.

Letters expressing views or urging action and other unsponsored written material regarding matters in issue in a hearing will be placed in the correspondence section of the docket of the proceeding. These data are not deemed part of the evidence or record in the hearing.

§ 81.67 Objections.

Objections to evidence shall be timely and briefly state the ground relied upon.

§ 81.68 Exceptions to rulings of presiding officer unnecessary.

Exceptions to rulings of the presiding officer are unnecessary. It is sufficient that a party, at the time the ruling of the presiding officer is sought, makes known the action which he desires the presiding officer to take, or his objection to an action taken, and his grounds therefor.

§ 81.69 Official notice.

Where official notice is taken or is to be taken of a material fact not appearing in the evidence or record, any party, on timely request, shall be afforded an opportunity to show the contrary.

§ 81.70 Public document items.

Whenever there is offered (in whole or in part) a public document, such as an official report, decision, opinion, or published data issued by any of the executive departments (or their subdivisions), legislative agencies or committees, or administrative agencies of the Federal Government (including Government-owned corporations), or a similar document issued by a State or its agencies, and such document (or part thereof) has been shown by the offeror to be reasonably available to the public, such document need not be produced or marked for identification, but may be offered for official notice, as a public document item by specifying the document or relevant part thereof.

§ 81.71 Offer of proof.

An offer of proof made in connection with an objection taken to any ruling of the presiding officer rejecting or excluding proffered oral testimony shall consist of a statement of the substance of the evidence which counsel contends would be adduced by such testimony; and, if the excluded evidence consists of evidence in documentary or written form or of reference to documents or records, a copy of such evidence shall be marked for identification and shall accompany the record as the offer of proof.

§ 81.72 Appeals from ruling of presiding officer.

Rulings of the presiding officer may not be appealed to the Reviewing Authority prior to his consideration of the entire proceeding except with the consent of the presiding officer and where he certifies on the record or in writing that the allowance of an interlocutory appeal is clearly necessary to prevent exceptional delay, expense, or prejudice to any party, or substantial detriment to the public interest. If an appeal is allowed, any party may file a brief with the Reviewing Authority within such period as the presiding officer directs. No oral argument will be heard unless the Reviewing Authority directs otherwise. At any time prior to submission of the proceedings to it for decision, the Reviewing Authority may direct the presiding officer to certify any question or the entire record to it for decision. Where the entire record is so certified, the presiding officer shall recommend a decision.

§ 81.73 Official transcript.

The Department will designate the official reporter for all hearings. The official transcripts of testimony taken, together with any exhibits, briefs, or memoranda of law filed therewith shall be filed with the Department. Transcripts of testimony in hearings may be obtained from the official reporter by the parties and the public at rates not to exceed the maximum rates fixed by the contract between the Department and the reporter. Upon notice to all parties, the presiding officer may authorize corrections to the transcript which involve matters of substance.

§ 81.74 Record for decision.

The transcript of testimony, exhibits, and all papers and requests filed in the proceedings, except the correspondence section of the docket, including rulings and any recommended or initial decision shall constitute the exclusive record for decision.

§ 81.75 Posthearing briefs; proposed findings and conclusions.

(a) The presiding officer shall fix the time for filing posthearing briefs, which may contain proposed findings of fact and conclusions of law, and, if permitted, reply briefs.

(b) Briefs should include a summary of the evidence relied upon together with references to exhibit numbers and pages of the transcript, with citations of the authorities relied upon.

§ 81.76 Service on amici curiae.

All briefs, exceptions, memoranda, requests, and decisions referred to in this part shall be served upon amici curiae at the same time and in the same manner required for service on parties. Any written statements of position and trial briefs required of parties under § 81.57 shall be served on amici.

§ 81.77 Conduct.

Parties and their representatives are expected to conduct themselves with honor and dignity and observe judicial standards of practice and ethics in all proceedings. They should not indulge in unseemly conduct. A representative of any party whether or not a lawyer shall observe the traditional responsibilities of lawyers as officers of the court and use his best efforts to restrain his client from improprieties in connection with a proceeding.

§ 81.78 Improper conduct.

With respect to any proceeding it is improper for any interested person to attempt to sway the judgment of the Reviewing Authority by undertaking to bring pressure or influence to bear upon any officer having a responsibility for a decision in the proceeding, or his decisional staff. It is improper that such interested persons or any members of the Department's staff or the presiding officer give statements to communications media, by paid advertisement or otherwise, designed to influence the judgment of any officer having a responsibility for a decision in the proceeding, or his decisional staff. It is improper for any person to solicit communications to any such officer, or his decisional staff, other than proper communications by parties or amici curiae.

§ 81.79 Ex parte communications.

Only persons employed by or assigned to work with the Reviewing Authority who perform no investigative or prosecuting function in connection with a proceeding shall communicate ex parte with the Reviewing Authority, or the presiding officer, or any employee or person involved in the decisional process in such proceedings with respect to the merits of that or a factually related proceeding. The Reviewing Authority, the presiding officer, or any employee or person involved in the decisional process of a proceeding shall communicate ex parte with respect to the merits of that or a factually related proceeding only with persons employed by or assigned to work with them and who perform no investigative or prosecuting function in connection with the proceeding.

§ 81.80 Expeditious treatment.

Requests for expeditious treatment of matters pending before the presiding officer or the Reviewing Authority are

deemed communications on the merits, and are improper except when forwarded from parties to a proceeding and served upon all other parties thereto. Such communications should be in the form of a motion.

§ 81.81 Matters not prohibited.

A request for information which merely inquires about the status of a proceeding without discussing issues or expressing points of view is not deemed an ex parte communication. Such requests should be directed to the Civil Rights hearing clerk. Communications with respect to minor procedural matters or inquiries or emergency requests for extensions of time are not deemed ex parte communications prohibited by § 81.79. Where feasible, however, such communications should be by letter with copies to all parties. Ex parte communications between a respondent and the presiding officer, the Reviewing Authority or the Secretary with respect to securing such respondent's voluntary compliance with any requirement of the statutes to which this Part applies or their implementing regulations.

§ 81.82 Filing of ex parte communications.

A prohibited communication in writing received by the Secretary, the Reviewing Authority, or by the presiding officer, shall be made public by placing it in the correspondence file of the docket in the case and will not be considered as part of the record for decision. If the prohibited communication is received orally, a memorandum setting forth its substance shall be made and filed in the correspondence section of the docket in the case. A person referred to in such memorandum may file a comment for inclusion in the docket if he considers the memorandum to be incorrect.

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PART IV

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

CACAO PRODUCTS AND CONFECTIONERY

Good Manufacturing Practice

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 128c—CACAO PRODUCTS AND CONFECTIONERY

Good Manufacturing Practice

In a notice published in the FEDERAL REGISTER of November 26, 1973 (38 FR 32554), the Food and Drug Administration proposed a regulation governing good manufacturing practices for cacao products and confectionery. The proposed regulation identified the types of food products to be included and set forth what the Commissioner of Food and Drugs regarded as good manufacturing practice in the manufacture, packaging, storage, transportation, and distribution of these products. The intent of the proposed regulation was to identify those materials, equipment, conditions, and operations that would receive the Commissioner's attention in fulfilling certain of his responsibilities under the Federal Food, Drug, and Cosmetic Act to prevent the introduction of adulterated foods into commercial channels. This notice promulgates a final regulation on this matter. The order becomes effective August 4, 1975, with an extension to December 1, 1975, granted when certain significant problems in implementation exist.

A period of 60 days was provided for the filing of comments on the proposal. In response to a request by industry, the comment period was extended by notice of February 1, 1974 (39 FR 4113), to 90 days ending on February 25, 1974.

Eighteen letters, each containing one or more comments on the proposal, were received from manfuacturers and processors, trade associations, suppliers, and other interested persons.

1. Four comments were basically in favor of the regulation and found the proposal generally satisfactory.

2. One comment suggested that separate GMP's be proposed for cacao products and confectionery in order to treat the "special characteristics" of each properly.

The Commissioner considered the suggestion but, based on industry association recommendations and other considerations, he concluded that a single regulation would be appropriate, particularly for the many manufacturers who process cacao products either in addition to or in conjunction with their confectionery operations.

3. Several comments expressed the view that many provisions of the proposed good manufacturing practice regulation under Part 128c properly belong in Part 128, frequently referred to as the "umbrella" GMP. The statement was made that some provisions of the proposed regulation are not necessarily unique to cacao products and confectionery but are applicable to foods in general. Specific references were made to §§ 128c.3, 128c.4 (e) and (f), 128c.5, 128c.6 (a) and (c), 128c.7 (e) and (f), and 128c.8. Sections 128c.4 (e) and (f) and 128c.7 (e) and (f) are, respectively, §§ 128c.4 (d) and (e) and 128c.7 (d) and (e) in the final order.

The Commissioner concludes that the provisions and requirements incorporated into the proposed Part 128c are designed for and lend specific direction to the processing of cacao products and confectionery. Moreover, as stated in the preamble to the proposal, the Commissioner intends to propose amendments to 21 CFR Part 128 at a later time which will provide more current guidance to the entire food industry.

4. Five comments stated that the proposal is discriminatory in singling out the cacao products and confectionery industries for a supplemental GMP. The nature of the comments was that supplemental GMP's should be proposed for segments of the food industry, based on the degree of hazard they represent, and that they should be truly applicable, appropriate, and nondiscriminatory. It was also suggested that the rest of the food industry should be required to meet the standards established in Part 128c.

As stated previously, the Commissioner intends to propose specific GMP's for individual segments of the food industry and also to propose amendments to Part 128 to provide more current guidance to the entire food industry on plant sanitation practices, as warranted. GMP's have already been promulgated for other segments of the food industry and more are in preparation. Consequently, the cacao products and confectionery industries were not singled out but are simply among the earlier segments of the food industry for which specific GMP's are being proposed.

5. One comment suggested that, because of the future implications of Part 128c, the proposal constitutes "latent" regulations for all segments of the food industry without their being properly alerted or having proper opportunity to participate or comment.

The Commissioner notes that long established and accepted procedures for promulgating regulations were followed in announcing the proposed GMP and observes that the comments received included some from companies and a trade association in which confectionery does not represent a major interest. The comment period was extended in response to a request by an industry association and there were no requests for further extension. Moreover, as GMP's are formulated for other segments of the food industry they will be published first as proposals with opportunity for comment.

6. Several comments questioned the statutory authority of the Food and Drug Administration to promulgate certain provisions of Part 128c. Among these are the replacement of some advisory "should" provisions in the "umbrella" GMP under Part 128 with mandatory "shall" provisions, the incorporation of the principle of "critical control points," the requirement for recordkeeping, and the reference to surveillance of records. Some comments referred to pending legislation which deals with the latter subjects.

The Commissioner's authority to promulgate these provisions derives from section 701(a) of the act. He has presented this regulation for cacao products and confectionery to promote the efficient enforcement of section 402 of the act, which pertains to food filth and safety. Of course, the regulation will be revised as may be required by future legislation that is enacted. With respect to "critical control points" and the requirement for recordkeeping, these subjects are discussed further in paragraphs 10 and 88.

7. Ten comments were directed at those requirements of Part 128c which were judged to be overly strict and rigid. Some of these comments identified cacao product and confectionery manufacture as low hazard industries and stated that stringent requirements are not warranted or that they would be financially ruinous to much of the industry. It was recommended that they be replaced by general guidelines comparable to those in the "umbrella" GMP or that certain mandatory "shall" requirements be changed to recommended or advisory "should" provisions. Specific reference was made to §§ 128c.3, 128c.4 (a) and (b), 128c.5(c), 128c.7 (c), (e), and (f), and 128c.8. It was stated that a relaxation of the requirements is necessary to maintain the cooperative effort between the Food and Drug Administration and industry. Section 128c.7 (e) and (f) is § 128c.7 (d) and (e) in the final order.

The Commissioner points out that all provisions which he considers to be essential for protecting consumers are mandatory and that advisory provisions are used in all other instances. He further points out that the requirements state what is to be accomplished and provide flexibility by allowing the manufacturer to choose alternative means whereby he may achieve compliance. The Commissioner recognizes that compliance with these requirements may require an investment of resources but considers them as necessary and appropriate for compliance with the law.

8. Five comments took exception to the sentence in the preamble to the proposal which reads, "The unique characteristics of cacao products and confectionery * * * require that special consideration be given to processing methods and sanitary controls * * *". The statement was described as false and misleading by implying that cacao products and confectionery are high risk products.

The Commissioner did not intend to imply that cacao products and confectionery are or are not high risk products, but rather that special considerations must be given to their processing in order to accommodate any unique properties and to eliminate potential hazards. Among the more important unique properties is the necessity for maintaining dry conditions in cacao product operations. Whereas water may be used freely in processing some foods, it must be restricted in the production and cleaning

operations associated with chocolate manufacture. Its presence may create conditions conducive to the growth of microorganisms. On the other hand, because of the low moisture environment, microorganisms which may be present are more resistant to destruction by heat.

The absence from the preamble to the proposal of a direct reference to microbial contamination was not meant to infer that cacao products and confectionery are free of the possibility of its occurrence. Since the writing of the proposal, there have been three occurrences of the presence of *Salmonella* in confectionery items containing milk chocolate which necessitated recall of the contaminated products. One involved candy produced domestically and two were of imported confectionery that were implicated in illnesses. Follow-up inspection of one foreign producer disclosed the presence of *Salmonella* organisms in the plant, on equipment, on cacao beans, and on in-line products. These occurrences point up the fact that continued surveillance is necessary in the production of cacao products and confectionery to maintain the good manufacturing practices that ensure the safety, cleanliness, and wholesomeness of these products. Documentation of the recall actions referred to above has been placed on display at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, for public review.

9. Nine comments stated that the statistics presented in the preamble regarding the compliance of the industry to FDA requirements were misleading, unrepresentative, and unsupported. They felt that more detail should have been presented regarding the basis for the inspections, the criteria used for evaluating the stated insanitary conditions, and the outcome of the legal actions cited.

The Commissioner explains that because of the volume of the supporting material, the information was presented in summary fashion with the statement that reports and other references cited were placed on display in the office of the Hearing Clerk for public review. The data were presented to point out that insanitary conditions do exist and to demonstrate the need for a GMP that would benefit both industry and consumers. The legal actions cited in the preamble to the proposal covered a 13-month period which ended in February 1973. During the ensuing period ending in April 1974, there were an additional 5 legal actions confirmed by notices of judgment involving manufacturers and dealers of confectionery and a deal of cacao beans as a raw material. These violations involved storage under insanitary conditions, or adulteration by filth or extraneous matter. Copies of the notices of judgment have been placed on file for public review at the office of the Hearing Clerk.

10. Five comments expressed concern over the use of the term "critical control points" in the proposal. They either asked that the term be clarified or questioned the appropriateness of its use on the grounds that "critical control points" should relate only to health hazards whereas GMP's should be concerned only with aesthetic or nonhealth matters.

The Commissioner recognizes from the comments that there is some confusion regarding the terms "critical control points" and "good manufacturing practice." He emphasizes that there is basically no distinction between them. Critical control points identify processes, practices, or conditions that present a potential for causing a food to be dangerous, filthy, or otherwise unsuitable for food use. Good manufacturing practices represent a code of procedures designed to control these points. The good manufacturing practice regulations are intended to implement certain provisions of the act relating to adulterated food, and the failure of a manufacturer to identify critical control points and to adopt good manufacturing practices which control these points may result in violations of section 402(a) of the act. Moreover, the Commissioner points out that the scope of good manufacturing practice regulations is not restricted to aesthetic or nonsafety factors as implied by some of the comments but also relates to safety.

Cacao Products

11. Two comments recommended that provision be made in the definition for "cacao products" under § 128c.1(a) to exclude the raw cacao bean.

The Commissioner concurs in the recommendation because he does not regard the raw agricultural commodity to be within the scope of the definition for cacao products. Accordingly, he has made an appropriate addition to the definition in the final order.

12. One comment recommended that flavorings and extracts derived from the cacao bean be excluded from the definition of "cacao products."

The Commissioner recognizes that the manufacture of chocolate extracts and of flavorings derived from them represents a technology unlike the manufacture of cacao products, and that the GMP requirements are different. Therefore, he has excluded such extracts and flavorings from the definition of cacao products in the final order. For the same reason, he has excluded most chocolate- or cocoa-flavored foods. Products such as cake mixes and chocolate- or cocoa-flavored milk for which separate GMP's are appropriate are among these exclusions. The Commissioner also has expanded the definition for cacao products to delineate more clearly the types of food products that are included.

Confectionary

13. Two comments suggested narrowing the definition for "confectionery" under § 128c.1(b). One suggested changing "* * * candy and other food products * * *" to "* * * candy and similar food products * * *". The second comment suggested the addition of the words "* * * and generally consumed as such," to the definition to eliminate sauces, toppings, frostings, and cake decorations.

The Commissioner agrees that the definition of confectionery needs some clarification. He does not agree that toppings, frostings, and cake decorations should be excluded as they are generally regarded as confectionery. He has clarified the scope of the definition in the final order by revision and also by indicating examples of foods which are included or excluded. He recognizes that there yet may be uncertainties regarding the applicability of the regulation to specific products, and he will be glad to offer an opinion in answer to individual inquiries.

14. One comment stated that the phrase "* * * made basically from sweeteners * * *" is misleading and is not true of many confections, particularly nut products and chocolate.

The Commissioner points out that chocolate is included in the definition for "cacao products" under § 128c.1(a) rather than under paragraph (b). With respect to nut products, he considers the comment to be appropriate and has changed the definition for "confectionery" to make it applicable to products of this class which are not made basically from sweeteners.

15. One comment described the phrase "and often fashioned into attractive shapes or forms," as an unnecessary editorial comment and suggested that it be deleted.

The Commissioner agrees that the phrase is an unnecessary part of the definition and, accordingly, has deleted it.

16. In the Federal Register for February 1, 1974 (39 FR 4113), the Commissioner gave notice that the proposed Part 128c does not cover chewing gum. The exclusion of chewing gum has been added to the definition for confectionery in § 128c.1(b).

Lot

17. Two comments suggested that the definition of "lot" under § 128c.1(c) not be restricted to a day's production, in order to provide for lots of materials such as chocolate liquor, liquid sugar, or corn sirup which may be used for longer periods.

The Commissioner advises that the definition was intended to refer only to lots of finished product. He has revised the definition to clarify that point.

Mandatory Requirement and Recommended Procedures

18. One comment suggested that advisory provisions as defined in § 128c.1(f) are inappropriate in governmental regulations where noncompliance would constitute violation of the law. In light of this consideration, it was suggested that all provisions be made mandatory.

The Commissioner points out, as he has previously, that all provisions which he considers to be essential for protecting consumers are mandatory. However, he has seen fit to provide alternative means for meeting some of these requirements, and the alternatives are appropriately provided for in an advisory manner.

WASTE

19. One comment questioned, with respect to the definition of "waste" under § 128c.1(g), whether the filth or other contamination must actually be present in the products.

This was the intent of the definition of "waste" and the Commissioner has changed the definition to clarify that point. Possible alternatives to designating a product as waste are discussed below in paragraph 83.

20. Two comments described the term "filth" in the definition of "waste" as an unnecessary pejorative and recommended its deletion.

The Commissioner does not consider the use of the term "filth" in the definition of "waste" as being pejorative. Waste often contains filth and the use of a truthful term can hardly be considered as pejorative. However, the term does not appear in the revised definition for "waste" because it has been broadened to cover product rejected due to adulteration of any kind.

PLANTS AND GROUNDS

21. One comment asked who is responsible for determining when the mandatory requirement for separating operations under § 128c.3 shall be implemented. The question was prompted by the "wherever necessary" condition which introduced the section. Similar comments were made with respect to comparable provisions in §§ 128c.7(c)(7), (c)(8), and (d). Section 128c.7(d) is § 128c.7(c)(11) in the final order.

The Commissioner considers that the requirement allows individual judgments by manufacturers to the extent that the objectives of the GMP are met. However, FDA will cooperate with industry in exercising judgment on these matters. The Commissioner has restated the requirement in the final order to avoid the uncertainty that resulted from the combination of "shall" and "wherever necessary." The section now requires, without the qualifying "wherever necessary," that effective measures be taken to prevent contamination of products, raw materials, or packaging materials. The several methods described for separating operations are offered as suggested approaches to achieving compliance. Comparable revisions were made in § 128c.7(c)(7) and (8) and are discussed in paragraphs 77 and 78 below. The response to the comment directed at § 128c.7(d) is presented in paragraph 80 below.

22. One comment questioned whether the absence of a partition or other named method of separating operations constitutes a violation of section 402(a)(4) of the act.

The Commissioner observes that the absence of a partition may contribute to a violation of section 402(a)(4) of the act but that such absence, of itself, would not necessarily constitute a violation. The determination of whether or not a violation exists would depend on the particular conditions existing at the plant.

23. One comment said that § 128c.3 adds desirable specifics, but asked if this section does not apply essentially to cacao bean processing.

The Commissioner points out that only paragraphs (c) and (d) of this section refer exclusively to cacao bean and cacao product processing but that the remaining paragraphs are applicable to confectionery operations as well.

24. One comment stated that existing building codes and fire regulations would prohibit partitions in certain areas. Another comment requested a more careful description of partitions as it was felt that they are the scourge of most food plants and often acquire hidden reservoirs of food on which pests thrive. Two comments said that air flow separation is impractical in that it would require massive amounts of sterile air and would offer no benefit to the consumer.

The Commissioner points out that the separation of the indicated operations was not a mandatory requirement of the proposed regulation nor is it mandatory in the regulation as revised in the order. Instead, the regulation requires that effective measures be taken to prevent contamination. Separation is merely given as an example of one method for achieveing this goal. This section has been revised slightly to make this clearer.

EQUIPMENT AND UTENSILS

25. Six comments recommended that the provision for "corrosion-resistant" food-contact surfaces under § 128c.4(a) be amended to provide that the surfaces only be "maintained in a corrosion-free condition," since many manufacturers use cast iron, aluminum, and ordinary steel in their processing operations, and these materials can be maintained in a corrosion-free condition with minimum care often utilizing dry cleaning methods.

The Commissioner agrees that food-contact surfaces that are maintained in a corrosion-free condition are adequate for maintaining sanitary conditions and has changed the requirement accordingly.

26. One comment recommended establishing the following definition in § 128c.1 for "corrosion resistant": "Capable of maintaining original surface characteristics under the prolonged influence of the use environment, including the expected food contact and the normal use of cleaning methods, compounds and sanitizing solutions."

The Commissioner is of the opinion that the essence of the definition above is incorporated into § 128c.4(a) as revised in the order.

27. Three comments claimed that the word "nonabsorbent" in paragraph (a) would eliminate the use of wooden starch molding boards and paddles, which do not present a hazard if properly maintained.

The Commissioner agrees that it was not the intent of this section to eliminate the use of such equipment so long as it is properly maintained, and has made appropriate changes in this paragraph to allow for their use.

28. Three comments recommended amending § 128c.4(a), where it refers to "smooth material", to allow for equipment designed for abrasive action such as grinding, cracking, etc., and which is, through necessity, not smooth.

The Commissioner agrees that provision should be made for food-contact surfaces that are, of necessity, not smooth. Upon reconsideration, he also realizes that there are appropriate food-contact surfaces in addition to those intended for abrasive action, such as conveyor belts which are neither smooth nor nonabsorbent. He has therefore deleted the requirement for smooth and nonabsorbent food-contact surface materials. The Commissioner has, however, added a requirement that all food-contact surfaces shall be maintained so as to prevent product contamination.

29. One comment discussed the requirement that food-contact surfaces be made of materials that will not readily crack. It stated that a cracked plastic surface may not be a potential hazard if it is properly maintained and suggested changing § 128c.4(a) to recognize that there is an attrition rate of plastic equipment and utensils.

The Commissioner is of the opinion that cracked plastic surfaces are not suitable food-contact surfaces because of the potential which cracks provide for microbial accumulation and subsequent product contamination. He believes that § 128c.4(a), as revised, allows for the proper use of plastic ware in processing operations.

30. Two comments said that the term "Seams" should be changed to read "Permanent seams" in order to allow for seams that require movement to facilitate various product sizes and for doors and lids. One comment expressed the opinion that § 128c.4(b) as written would eliminate industry's standard "whip stitch" method for repairing belts, thus requiring what were considered to be costly and unnecessary replacements. It was also said that currently available belting materials do not have smoothly bonded articulations and that this requirement, as written, would eliminate the use of wire mesh belts in processing and packaging areas.

The Commissioner recognizes the need to consider access doors and lids, moveable seams, and belts, and has changed § 128c.4(b) accordingly to allow for their use with proper maintenance.

31. Three comments suggested changing the wording in paragraph (b) to emphasize the microbial problems that might occur where "inaccessible spaces exist in which dirt or organic material might accumulate" rather than emphasizing the mere presence of such spaces.

The Commissioner considers the recommendation to be appropriate and has revised the paragraph accordingly.

32. One comment suggested changing § 128c.4(c), which refers to nonfood-contact surfaces, to read, "All equipment shall be designed and constructed in such a manner as to minimize the retention of moisture and dust, the shelter of vermin

and soil, and to facilitate inspection, servicing, maintenance and cleaning," saying this is more definitive than the proposed requirement. A second comment suggested the wording "Nonfood-contact surfaces which could cause contamination of equipment shall be so constructed that they can be kept in a clean, sanitary condition."

The Commissioner concludes that the suggestions are inappropriate because, in his opinion, they would change the provision from its intended purpose as a simple statement of the clean condition required of nonfood-contact surfaces in contrast to the more detailed requirements in § 128c.4(a) for food-contact surfaces. However, the Commissioner concludes that the reference to the sanitary condition of nonfood-contact surfaces is inappropriate and has deleted it.

33. One comment recommended that the provision for dust control devices on equipment under § 128c.4(d) be made mandatory for consistency with other mandatory requirements in the proposal.

The Commissioner points out that § 128c.3, as revised in the final order, requires that effective measures be taken to prevent contamination of products, raw materials, or packaging materials. See paragraph 21 above. That section includes, for example, separation by enclosed systems among the alternative means for preventing contamination by dusty operations. The Commissioner recognizes the desirability of installing dust-control devices, but since they are obviously not the only means for preventing contamination by dust, he does not consider it appropriate to make such installations mandatory. Upon further consideration of the matter, he believes that § 128c.3 of the order covers the control of dusty operations adequately and makes it unnecessary to refer to dust control devices. He has therefore deleted paragraph (d) of § 128c.4 and has redesignated paragraphs (e), (f), and (g) as paragraphs (d), (e), and (f), repectively.

34. One comment on § 128c.4(e), § 128c.4(d) in the final order, said that FDA should identify the raw materials to be pasteurized.

The Commissioner advises that this provision is intended only to deal with the accuracy requirements for temperature regulating, measuring and recording devices on equipment used to pasteurize or otherwise control or prevent undesirable microbial growth in raw materials and finished products. Materials requiring pasteurization are detailed in § 128c.7(a)(1) of the regulation.

35. One comment considered the ±2° F tolerance for the accuracy of temperature controlling, measuring, and recording devices on equipment used to control or prevent undesirable microbial growth in food materials to be restrictive and recommended that the tolerance be changed to ±5° F if one must be established. The reason presented was that variations in temperature are not important as long as the temperature is maintained within the specified range.

The Commissioner believes that the tolerance on temperature controlling, measuring, and recording devices should be defined, whenever feasible, in order to maintain actual and observed temperatures within limits that are not misleading. He is therefore retaining the ±2° F tolerance for such devices on equipment used to control or prevent undesirable microbial growth in raw materials or finished products.

36. One comment recommended that temperatures be indicated in degrees Centigrade as well as degrees Fahrenheit to allow adjustment to the metric system.

Since American manufacturers presently use Fahrenheit thermometers to monitor their processes, the Commissioner sees no need at this time to include a Centigrade scale. Upon the adoption of the metric system, an across-the-board revision will be made of all regulations. In any event, conversion tables are readily available.

37. One comment regarding § 128c.4(f), § 128c.4(e) in the final order, requested that the requirements of this paragraph with respect to freezer and cold storage compartments used for storing or holding materials capable of supporting growth of microorganisms be changed so as not to apply to compartments that are present but not used for the stated purpose.

The Commissioner concludes that it is unnecessary to make the change requested because he regards the requirement as presently written to be clearly applicable only to those compartments which are actually used.

38. One comment agreed with the requirement that cooling tunnels have access doors or other provisions to permit cleaning of the interior and suggested that the requirement be presented as a separate paragraph.

The Commissioner agrees that the subject of cooling tunnels should be the subject of a separate paragraph and has accorded it attention as a new paragraph (f) under § 128c.4.

PERSONNEL SANITATION FACILITIES

39. Two comments regarded the provision for hand sanitizing preparations as a requirement for hand dip stations under § 128c.5(a). They claimed that in chocolate and candy manufacture, such wet facilities can be a source of trouble when located in certain processing areas or that the effectiveness of sanitizing solutions is negated by the necessity for drying the hands. Among the comments, one requested that the location of the sanitizing facilities be clarified and a second recommended that the requirement for them be deleted.

The Commissioner considers the use of hand sanitizing preparations as a necessary precautionary practice. He points out that the regulation requires only that the facilities be readily accessible and effective. Beyond that, the selection of type and location is left to the discretion of the manufacturer.

40. One comment expressed general agreement with the section on personnel sanitation but stated that hand washing facilities should be required in open production areas where unprotected food is handled in order to prevent recontamination from contact with doors and knobs. For the same reason, the comment recommended changing the provision for water control valves so designed and constructed as to prevent recontamination of clean, sanitized hands from advisory to mandatory.

The Commissioner notes that the regulation does not preclude the installation of hand washing and sanitizing facilities in production areas when feasible. However, their location is left to the discretion of the manufacturer because, as noted above, wet facilities in the production area can be a source of trouble in some processes. With respect to the design of water control valves, the Commissioner points out that paragraph (e) of § 128c.5 is a mandatory provision of the regulation intended to ensure that employees' hands are washed and sanitized under the circumstances described. The facilities must be designed so as to permit compliance with this requirement. The reference in paragraph (a) to the design of water control valves was included as guidance to the manufacturer as one approach to such compliance. If management can ensure that employees' hands are santized and not recontaminated before starting to work without using such equipment they are free to do so.

41. One comment recommended an addition to § 128c.5(a) to provide that waste receptacles be constructed in a clean, sanitary manner and be provided with covers.

The Commissioner has considered this comment and wishes to make it clear that the sanitary and safe condition of the food is his concern rather than the details relating to receptacles for refuse. Accordingly, he has revised paragraph (a) in the regulation to require that the receptacles be constructed and maintained so as to prevent product contamination. Within that limitation, he has left the details of their design and the use of covers to the discretion of the manufacturer. The Commissioner also has redesignated the receptacles as "refuse receptacles" to avoid confusion with the word "waste" which is defined in § 128c.1(g).

42. One comment requested the addition of a provision to clarify that gloves complying with the requirements of § 128.8(b)(4) of the "umbrella" GMP can be used.

The Commissioner is not making the addition requested because the regulation does not preclude the use of gloves when appropriate, and the conditions for their use are adequately covered by the "umbrella" GMP.

43. Four comments considered it management's responsibility to enforce the requirements for hand washing and sanitizing under § 128c.5(c). They indicated that it is not feasible in every operation to assign the responsibility to supervi-

sors or that to do so would be a step backward in management-employee relationships. They recommended either that the responsibility be assigned to management and/or supervisors or that the paragraph be reworded as a directive to the employees.

The Commissioner agrees that this responsibility properly belongs to management and has revised the regulation accordingly. The regulation does not preclude delegation by management of control of the operations, provided that the stated requirements are met.

44. One comment suggested that an impossible burden would be imposed on supervisory personnel if they are required to ensure that employees wash and sanitize their hands under all necessary circumstances. The comment thus recommended changing the phrase "to ensure" to "so that." It also recommended making the requirement applicable when hands have actually become soiled or contaminated rather than when they may have become soiled or contaminated.

The Commissioner believes that the burden of complying with this provision of the regulation is no less a responsibility of management than is compliance with its other provisions. With the method for implementing the required control left to the discretion of the manufacturer, the Commissioner regards the requirement as a reasonable one as well as a necessary one. He rejects the suggestions for modifying the requirement because the changes suggested would negate its effectiveness. It is not always possible to tell by examination when employees' hands have become contaminated as such contamination is often not present as visible soil. It is therefore necessary to use the more general requirements set forth in the regulation.

45. Two comments asked what degree of supervision is necessary to satisfy the requirement for "sufficient control" over hand washing and sanitizing operations.

The Commissioner advises that "sufficient control" is whatever is necessary to see that employees wash and sanitize their hands. This may be a supervisor's visual observation and control or any other effective means.

EQUIPMENT AND UTENSIL CLEANING AND SANITIZING

46. One comment suggested that § 128c.6, which deals with equipment and utensil cleaning and sanitizing, should be expanded to include unused equipment and spare parts.

The Commissioner rejects the suggestion to expand the section because he considers those items actually used as the principal ones presenting a direct potential for contaminating products. The provisions of this section would of course apply to unused equipment and spare parts when they are put into use.

47. One comment requested definition of the terms "cleaning" and "sanitizing" in § 128c.6(a) and asked if everything need be sanitized.

The Commissioner points out that the term "sanitize" is defined in § 128.1(c) of the "umbrella" GMP as the "adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other microorganisms". The term "cleaning" is intended to convey its commonly accepted meaning of removing dirt, filth, and extraneous matter from surfaces. Sanitization of equipment is necessary to the extent that it is needed to prevent product contamination.

48. One comment stated that there is no reason to single out "corn sirup" under § 128c.6(b) and suggested that it be changed to read "nutritive sweeteners in liquid form."

The Commissioner agrees with the comment and has made an appropriate change in the paragraph.

49. One comment was critical of the sentence in § 128c.6(b) pertaining to possible microbial problems associated with the wet cleaning of certain equipment because it does not mention "sanitize".

The Commissioner points out that the requirement in the first sentence of this paragraph for maintaining food-contact surfaces of equipment in a sanitary condition applies to all equipment, whether cleaned by wet or dry methods.

50. One comment recommended rewording the limitation on the use of wet cleaning methods in § 128c.6(b) to permit properly used wet cleaning methods where microbial growth could be a problem due to improper use of wet cleaning methods.

The Commissioner does not agree that this provision needs revision since the requirement as written in the regulation does not preclude wet cleaning performed in a manner that does not introduce a microbial problem.

51. One comment stated that FDA should spell out specific conditions which "shall" be observed in the handling of insecticides under § 128c.6(c) since they are not spelled out in Part 128.

The Commissioner believes it is impossible to give detailed instructions in this regulation for the numerous permitted applications of pesticides in their multitude of compositions, physical forms, and use levels. He considers it to be the manufacturer's responsibility to use only those pesticides bearing a label statement providing for use in food manufacturing areas and, also, to use them within the label restrictions. Questions regarding their use should be referred to the pesticide supplier or to the Environmental Protection Agency. The food manufacturer must not use a pesticide if safe conditions for its use cannot be devised to preclude product contamination.

PROCESSES AND CONTROLS

52. One comment asked whether the quality control requirements of the introductory paragraph to § 128c.7 are a peculiar need of confectionery processing and if so, why the need was not spelled out in the preamble.

The Commissioner explains that the requirements of this paragraph are applicable generally to most foods and that their recital at this point in the regulation was intended as an introduction to the more specific requirements for cacao products and confectionery enumerated in the paragraphs which follow in § 128c.7. With respect to identifying the need for these requirements in the preamble to the proposal, the Commissioner points out that earlier the preamble included a discussion of legal actions against adulterated cacao products and confectionery, of consumer complaint letters, and of noncompliance of some cacao product and confectionery manufacturing plants with good manufacturing practices. These examples illustrated that adequate quality control was obviously lacking in the processing of some of these products.

53. One comment stated that paragraph (a) of § 128c.7 pertaining to the handling of raw materials neither provides guidance nor clarifies responsibilities and is superfluous because its requirements are provided for in the act.

The Commissioner does not agree and notes that paragraph (a) gives specific direction not covered elsewhere for handling raw materials used in cacao products and confectionery manufacturing. The paragraph also allows the use of alternative methods for ensuring the safety and wholesomeness of the product.

54. A comment suggested that § 128c.7 (a) and (b)(4) outline bad manufacturing practices in that they allow for purification of materials and killing of pathogens during processing rather than emphasizing purity of raw materials. The acceptability of purchasing under a supplier's guarantee was also questioned.

The Commissioner points out that the manufacturer is responsible for ensuring that his finished product is safe, clean, wholesome, and free of pathogenic microorganisms. Whether the manufacturer chooses to pasteurize raw materials before or during use or to purchase them under a supplier's guarantee or whether he choses to analyze the materials to verify that they are in compliance is his prerogative. The Commissioner considers any of these alternatives to be consistent with good manufacturing practices.

55. Three comments suggested a change in the wording of the last sentence of paragraph (a)(1), (2) and (3), which identifies alternative methods for complying with the requirements of the respective subparagraphs. The comments pointed out that analyzing materials for pathogenic microorganisms is not a method for accomplishing compliance with the requirements but serves only to establish whether materials are or are not in compliance. It was also suggested that the statement would be more definitive and less ambiguous if the word "This" were replaced by "These requirements."

The Commissioner concurs with the substance of these comments and has reworded the sentence in question in each subparagraph to clarify its meaning.

56. Two comments suggested the addition of an appropriate provision that would relate the requirements of § 128c.7(a)(1) to Food and Drug Administration guidelines for natural or unavoidable defects with respect to pathogenic microorganisms. It was stated that such a provision would permit deferring to future definitions a decision as to what a pathogen is. A third comment stated that ensuring freedom from pathogens would be impossible based on statistical testing.

The Commissioner points out that no tolerance is allowed for pathogens in foods and, consequently, there are no applicable FDA guidelines for such contamination. With respect to the definition of pathogenic microorganisms, the Commissioner considers them to be microorganisms capable of causing illness or disease in humans. The Commissioner realizes that statistical testing will not ensure absolute freedom from pathogens. By promulgating GMP's, the Commissioner is attempting to incorporate procedures into food manufacturing that will avoid pathogens in finished products. The statistical testing methods being used are designed to measure the effectiveness of these procedures. The Commissioner believes that this system represents the most feasible approach currently available for protecting the consumer from pathogens.

57. One comment recommended that the first sentence in § 128c.7(a)(1) be clarified so as to indicate that the word "materials" in the sixth line includes all of those previously mentioned.

The Commissioner has adopted the recommendation by inserting "(i.e., milk, milk products, and egg products)" after the word "materials."

58. One comment stated that because of the inclusion of corn meal among the raw materials identified as being susceptible to aflatoxin contamination under § 128c.7(a)(2), the entire text of this subparagraph belongs in the "umbrella" GMP.

It was the Commissioner's intent to make this subparagraph informative to manufacturers of cacao products and confectionery by including a comprehensive list of food materials presently known to be susceptible to aflatoxin contamination. Since these materials are used in relatively few commodities, the Commissioner does not believe their listing in the "umbrella" GMP is warranted.

59. One comment considered aflatoxins too important to be linked to natural or unavoidable defects and criticized the use of action levels to control aflatoxins.

The Commissioner advises that because aflatoxins are clearly poisonous or deleterious substances, the phrase "poisonous or deleterious substances" has been substituted for the phrase "natural or unavoidable defects".

The Commissioner also explains that enforcement of established action levels has been effective in controlling aflatoxin contamination. Action levels are as enforceable as tolerances. These levels are subject to revision as new information and improved methodology pertaining to aflatoxins become available.

60. One comment suggested inserting the word "pathogenic" before "microorganisms" in § 128c.7(a)(3) for consistency with paragraph (a)(1).

The Commissioner points out that whereas paragraph (a)(1) pertains specifically to pathogenic microorganisms, paragraph (a)(3) is concerned with contamination by other microorganisms.

61. One comment stated that more specifics are needed regarding unavoidable defect action levels and sieve requirements for materials described in § 128c.7(a)(3).

The Commissioner points out that defect action levels that have been established for many materials for reasons of aesthetics are applicable to cacao products and confectionery without their specific incorporation in this regulation. Revisions of and amendments to these action levels also would be applicable. The Commissioner concludes that reference to Food and Drug Administration action levels and the provision in paragraph (c)(7) and (8) of § 128c.7 for the use of equipment to remove extraneous materials are adequate for this GMP regulation.

62. One comment labeled the action levels as outdated and said their existence provides a source of contamination. It was stated that such action levels do not meet good manufacturing requirements for raw materials or finished products.

The action levels being used are based on the best information available to the Commissioner at this time. These action levels are being updated as fast as new data can be obtained. The Commissioner believes that compliance with these regulations is in accordance with current good manufacturing practices and does not add avoidable contamination to food. The only alternative available is to use a zero level for such contamination which is not feasible since it would result in destruction of a large part of our food supply.

63. One comment questioned the value of holding raw materials in their original containers under § 128c.7(b), particularly if the containers are filthy or were previously stored under insanitary conditions.

The Commissioner did not intend to imply a special significance to "original containers" and so has deleted this term with the understanding that original containers may be suitable in some cases for holding raw materials. He also has added to the paragraph a requirement that containers for holding raw materials be maintained so as to prevent raw material contamination.

64. One comment said it was necessary to change the term "prevent" in the first sentence of § 128c.7(b) to "deter" or "resist" because it was felt that 100 percent exclusion of contaminants, as inferred by the term "prevent," is impossible in commercial food production. Similar comments questioned the use of the word "prevent" in § 128c.7(c)(10) which deals with the prevention of contamination during the cracking of cacao beans and in § 128c.7(f), redesignated § 128c.7(e) in the final order, which deals with warehousing and distribution.

The Commissioner does not agree and he is retaining the word "prevent". He points out that the intent of paragraph (b) is to prescribe storage conditions which will ensure that raw materials will be in compliance with the provisions of the act as they relate to adulterated foods. The impetus should be toward preventing contamination and any lesser direction would be inappropriate. The same reasoning applies to paragraph (c)(10) and to paragraph (f), paragraph (e) in the final order.

65. One comment said the prevention of decomposition, as required by § 128c.7(b), is impossible because decomposition is a dynamic process which occurs as soon as a product is grown or harvested.

The Commissioner has changed the sentence in question to read in part, "* * * to prevent their adulteration due to contamination or decomposition." He believes that this change will clarify the point so that decomposition now refers to deteriorative changes from an initial condition sufficient to constitute adulteration.

66. One comment requested a definition of the "short periods of time" that materials capable of supporting growth of pathogenic microorganisms need not be stored as indicated under § 128c.7(b)(1).

In order to clarify this point the Commissioner has rephrased the statement to read in part, "* * * except for such period of time actually required for the processing involved and which does not affect the wholesomeness of the raw materials."

67. Three comments stated that temperatures of 0° F or below in § 128c.7(b)(2) are not necessary for storing many frozen materials and that higher temperatures such as 20° F are adequate for this purpose.

The Commissioner points out that paragraph (b)(2) requires only that frozen materials be kept frozen and recommends that the storage temperature be 0° F or below.

68. A comment requested more detail on the filtered air-intake vents on storage tanks for liquid sugars under § 128c.7(b)(3). The comment questioned whether they should be dust tight or be capable of excluding mold and bacteria.

The Commissioner concludes that such detail is not warranted in the regulation and leaves to the manufacturer the selection of filters that will prevent contamination.

69. One comment noted the absence of a reference to the use of ultraviolet lights as a means of controlling microbial growth, particularly as it might apply to controlling mold in tanks of liquid sugars.

The Commissioner points out that ultraviolet lights may be used in addition to air-intake filters if they are considered necessary to prevent microbial growth.

70. Three comments recommended deleting one or more subdivisions of

§ 128c.7(b)(4), which list alternative means for precluding the growth of pathogenic microorganisms in liquid mixtures containing perishable materials. The means described were said to be expensive, wasteful, and unnecessary for all but the most sensitive materials.

The Commissioner considers it important to require, as does this subparagraph, that measures be taken either to preclude the growth of pathogenic microorganisms or to destroy them in these liquid mixtures. The alternative holding and processing methods which follow the requirement are merely advisory procedures for achieving the required freedom from these microorganisms.

71. One comment requested an addition to § 128c.7(c)(1) to allow for defrosting of frozen egg products by the quickest method possible which does not significantly increase the microbial load.

The Commissioner is not incorporating the addition requested because he does not believe it represents a significant change in the requirements of this subparagraph. He points out that the regulation merely requires that frozen egg products be defrosted in a sanitary manner and by such methods that their wholesomeness is not adversely affected. The indicated time and temperature limitations are presented as advisory procedures.

72. Three comments on § 128c.7(c)(3) and (4) asked how long rework can be stored or held before it is required to be examined as a raw material before reprocessing.

The Commissioner considers that the diverse nature of materials that might be defined as rework and the rework storage or holding conditions are such that a time limit cannot be specified for holding rework without possible reexamination. He has modified § 128c.7(c)(3) so that both rework and return are considered as raw materials. Examination and testing of rework and return shall be carried out as necessary to implement quality control procedures for preventing product contamination (§ 128c.7).

73. One comment with reference to § 128c.7(c)(3) and (4) suggested the addition of a requirement that containers for rework and waste be emptied and steam-cleaned daily.

The Commissioner has amended § 128c.7(c)(3) and (4) to state clearly the requirements and to suggest methods whereby they may be met. He agrees that the daily emptying and steam cleaning of containers for rework and waste may prevent product contamination and is not precluded by the regulation. However, any method that keeps the waste from contributing directly or indirectly to product contamination is satisfactory, and the Commissioner can see no useful purpose in insisting on a single method.

74. One comment suggested that in § 128c.7(c)(5), the wording of the phrase "* * * cross-contamination between * * * these materials and refuse" be reversed so as to read, "* * * cross-contamination between * * * refuse and these materials," thus indicating that refuse is the source of contamination.

The Commissioner has made this change in the order for the reason stated.

75. One comment requested clarification as to the type of protection against contamination that is required by § 128c.7(c)(5).

The Commissioner is not making such an addition to § 128c.7(c)(5) because he is of the opinion that the type of protection used to prevent contamination should be decided by the manufacturer.

76. One comment considered the reference to cross-contamination to be unnecessary because of the provision in § 128c.3 for separating operations to prevent contamination.

Although the Commissioner agrees that there may be some repetition, he is retaining the reference to cross-contamination in § 128c.7(c)(5) because he believes that it amplifies and lends desirable emphasis to the provisions of § 128c.3, particularly with respect to contamination from refuse and to protection of materials transported by conveyor, which are not specifically mentioned elsewhere in the regulation.

77. Three comments on § 128c.7(c)(7) and (8) asked who will determine when and what devices shall be utilized to prevent the inclusion of metal or other extraneous material in the finished product as required by paragraph (c)(7). The comments considered that it should be management's responsibility to make those decisions.

The Commissioner agrees that it is the manufacturer's responsibility to establish the detailed conditions that define processing operations that are necessary for meeting stated requirements of the regulation. Section 128c.7(c)(7) has been revised in the order to remove the phrase "where necessary" which appears to have been a source of uncertainty for those who commented.

78. One comment stated that § 128c.7(c)(7) and (8) should be more specific concerning sieve sizes, their manners of use, and other details to make these paragraphs definitive of good or bad manufacturing processes.

As indicated above, the Commissioner considers it to be the manufacturer's responsibility to establish these points based on specific needs. Also, for the reason given above, § 128c.7(c)(8) has been revised to omit the phrase "whenever necessary."

79. One comment suggested that under § 128c.7(c)(10) the handling and holding of materials resulting from cacao bean cracking operations, in a manner to prevent product contamination, can be facilitated by holding them in a separate building.

The Commissioner views the comment as expressing one method of meeting this requirement but points out that the regulation as proposed would permit the use of this procedure or any other that is effective in preventing product contamination.

80. One comment stated that in § 128c.7(d) the word "shall" which introduces the requirement for testing is incompatible with the "as necessary" condition which follows it.

The Commissioner recognizes that the combination of "shall" and "as necessary" may lead to uncertainty as to the circumstances when testing would be called for and, also, as to the required frequency of testing. In view of the fact that appropriate quality control procedures are required by the introductory paragraph of § 128c.7, the Commissioner has reconsidered the matter of testing. He has concluded that a specific provision for testing is unnecessary and, accordingly, has deleted it from the regulation. The remaining provisions of § 128c.7(d) of the proposal relating to the disposal or reconditioning of adulterated material have been redesignated paragraph (c)(11). Paragraphs (e) and (f) have been redesignated paragraphs (d) and (e), respectively.

81. One comment on § 128c.7(d) recommended replacing the word "ensure" with "ascertain." It was asserted that 100 percent consumption of the product in testing would be required to ensure compliance with the requirement.

The deletion of the provision for testing (see paragraph 80 above) makes it unnecessary to consider the suggested change in wording.

82. One comment stated that the testing requirements of § 128c.7(d) would present manufacturers with a cost burden which, in some instances, may prove ruinous. The comment described the testing of both in-process materials and finished products as duplicative and stated that products might be ready for shipment before in-process test results are available.

Although the specific reference to testing has been deleted from the regulation (see paragraph 80 above), the Commissioner believes that testing may be a necessary part of an effective quality control program. He recognizes that in some instances it may be necessary to test both in-process materials and finished products to prevent contaminated products from being offered to consumers. He encourages the investment in testing in the absence of effective alternatives and points out that the required frequency and extent of testing are to be determined by the manufacturer based on his particular needs.

83. One comment was critical of the provision in § 128c.7(d) which permits, when feasible, the reconditioning of adulterated material. The comment was also critical of what it described as a complete dependence on reexamination of reconditioned materials for ensuring product purity.

The Commisisoner points out that the proposed regulation provides for reconditioning of adulterated material as an alternative to disposal only when reconditioning to a wholesome condition, as verified by examination, is feasible. The material must be disposed of when it cannot be restored to a condition that makes it suitable for use as human food. It is the Commissioner's view that these requirements are consistent with widely accepted good manufacturing practice.

84. One comment expressed the opinion that in the event or question of con-

tamination a manufacturer should be allowed the option of risking the loss of his entire inventory rather than having to comply with the requirement of § 128c.7(e) for mandatory coding of shipping containers.

The Commissioner points out that the purpose of coding is to expedite the recall of adulterated food and that the risks involved are not solely economic nor are they borne exclusively by the manufacturer. The Food and Drug Administration monitors the recall procedure as part of its role in protecting the public health, and the entire process can be expedited when questionable lots are identified by their code marks. Accordingly, this requirement is retained under § 128c.7(d) of the order.

85. Three comments recommended changes that would make the requirements for coding more flexible. One recommended revised wording to direct that code marks be at a readily visible location and not necessarily on the outer layer of finished product packages. A second comment suggested that code marks for identifying a packaging lot be allowed as an alternative to the identification of product lot. The stated purpose is to allow for meaningful coding of packages which contain mixtures of different product lots such as assorted chocolates. A third comment recommended that plant identification not be mandatory for products produced only in one plant.

The Commissioner has revised the regulation, as suggested by the first comment, to require that code marks on the finished product package be visible on the unopened package. He believes that the change removes the uncertainty as to what constitutes the outer layer and allows for greater flexibility in package coding. He has further changed the regulation to remove the mandatory requirement for placing the code marks on the shipping container and to provide the manufacturer with the flexibility to code either the shipping container or the finished product package, or both, if he so desires. The Commissioner also has revised the regulation to incorporate the second suggestion that identification of packaging lots be permitted as an alternative to identifying product lots. The alternative would be applicable to situations in which identification of product lot is impracticable or impossible, e.g., the coding of boxes containing assorted chocolates which may be manufactured in different departments on different dates. With reference to the third comment, the Commissioner is retaining the requirement for plant identification. When a product is implicated in a possible threat to consumer health, it is important, as indicated in paragraph 84 above, that the Commissioner be able to identify the point of manufacture as rapidly as possible. Inasmuch as coding of products is required in any event, the Commissioner believes that the complete coding required by the regulation does not impose an additional burden on the manufacturer.

86. Two comments requested a rewording of § 128c.7(f), § 128c.7(e) in the final order, to limit the manufacturer's responsibility for warehousing and distribution only to products being transported, stored, or held for sale in facilities under his control.

The Commissioner is of the opinion that the provisions in the regulation for controlling the storing, holding, and transporting of finished products are appropriate components of the GMP regulation whether or not each of these operations beyond the actual manufacturing stage is under the control of the manufacturer. In the event of a violation, the question of accountability would, of course, be resolved so that regulatory action would be directed at the responsible party. The course of action to be followed in implementing this regulation is neither unique nor a matter to be addressed within the regulation.

87. Another comment suggested that the provision for minimizing deterioration of product quality should be removed because it refers to aesthetic quality rather than product safety. According to the comment, the regulation of product quality goes beyond the scope of the GMP regulation and the statutory authority of the Food and Drug Administration.

The Commissioner agrees that deterioration of product quality is not related to the provisions of section 402(a) of the act and has therefore deleted that part of paragraph (f) (paragraph (e) in the order) pertaining to product quality.

88. One comment expressed concern that the broad recordkeeping requirements of § 128c.8 provide no protection of trade secrets or other confidential information.

The Commissioner agrees that deterio- safeguarding of confidential information that may be included among the records required by this section does not present a unique situation. The Food and Drug Administration will take adequate protective measures for such information as it does for the large volumes of other confidential information entrusted to it.

89. The Commissioner notes that paragraph (b) of § 128c.8 prescribes minimum periods of time that certain processing and production records shall be maintained, but that paragraphs (a) and (c) do not specify time periods for maintaining other required records. He considers it appropriate to apply the same time requirements uniformly to all records required by the regulation and has incorporated such a requirement in a new paragraph (d) of this section.

90. One comment suggested a rewording of § 128c.8(a) to require records of examinations or of suppliers guarantees or certifications, but not both.

The Commissioner rejects the suggestion and reaffirms the position that records of examinations and of guarantees or certifications shall be maintained for a specified period of time when such records exist. He points out, however, that there is no section of the regulation which requires the manufacturer both to perform examinations and to obtain guarantees or certifications on the same materials.

91. Two comments on § 128c.8(b) stated that the examination of processing and production records by the Food and Drug Administration should be restricted only to those situations where examination of these records is necessary for the protection of public health or if a specific health problem arises.

The Commissioner considers that the examination of records is intended to detect and correct deficiencies in processing or production before they manifest themselves as public health problems. This principle of prevention of problems by good manufacturing practice is the purpose of the regulation.

92. Two comments claimed that the requirement of § 128c.8(c) for maintaining records to identify the initial distribution of finished products would impose a costly burden on the manufacturer without benefit to the consumer.

The Commissioner is of the opinion that the benefits to the consumer from this requirement are clear. It would expedite the recall of dangerous or potentially dangerous products from the market. He considers the requirement to be a logical companion to the one for coding (discussed in paragraph 84 above), and that it serves the same purpose in protecting the public health. The rapid identification of suspected food lots by their code marks together with a knowledge of the meaning of the code marks and a knowledge of their distribution can make a recall much easier and faster and thus result in increased consumer protection.

The Commissioner has concluded that the proposal previously referred to, together with the comments received, form the basis for a good manufacturing practice regulation for cacao products and confectionery. In addition to amending the proposal to reflect the comments received, the Commissioner has modified portions of the proposal as he considered to be necessary for the implementation of the proposed regulation. Accordingly, having evaluated the comments received and other relevant material, the Commissioner concludes that the regulation should be promulgated as set forth below.

The Commissioner has set an effective date of August 4, 1975 for this final order. However, the Commissioner believes it is reasonable to extend the effective date in those instances where compliance with particular provisions requires the installation of equipment or facilities which are in short supply and where the manufacturer is able to demonstrate that this is causing significant problems to the extent he needs additional time for complete compliance. Where this is demonstrated, the Commissioner will grant an extension of the effective date for up to December 1, 1975.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a)(4), 409, 701(a), 52 Stat. 1046, 1055, 72 Stat. 1785–1788; 21 U.S.C.

342(a)(4), 348, 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), Chapter I of Title 21 is amended by adding a new Part 128c to read as follows:

PART 128c—CACAO PRODUCTS AND CONFECTIONERY

Sec.

AUTHORITY: Secs. 402(a)(4), 409, 701(a), 52 Stat. 1046, 1055, 72 Stat. 1785–1788 (21 U.S.C. 342(a)(4), 348, 371(a)).

§ 128c.1 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Cacao products" means any form of chocolate, chocolate product, cocoa, or cocoa product. Such foods include but are not limited to cacao nibs, sweet chocolate, milk chocolate, other foods standardized by Part 14 of this chapter, and chocolate sirup. They do not include the raw cacao bean, extracts, flavoring derived from such extracts, and chocolate- or cocoa-flavored foods.

(b) "Confectionery" means candy and other food products made with sweeteners, and frequently prepared with colorings, flavorings, milk products, cacao products, nuts, fruits, starches, and other materials. Such foods include but are not limited to frostings, toppings, and cake decorations. They do not include chewing gum, sauces, sirups, jellies, jams, preserves, cakes, or cookies.

(c) "Lot" means a collection of primary containers or units of the same size, type and style, containing finished product produced under conditions as nearly uniform as possible, designated by a common container code or marking, and, in any event no more than a day's production.

(d) "Return" means clean, wholesome product(s) returned to the manufacturer for reprocessing for reasons other than insanitary conditions and which is suitable for use as food.

(e) "Rework" means clean, wholesome product(s) removed from processing for reasons other than insanitary conditions and which is suitable for reprocessing and for use as food.

(f) "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(g) "Waste" means product rejected due to adulteration that renders it unsuitable for use as human food.

§ 128c.2 Current good manufacturing practice.

(a) The criteria and definitions in Part 128 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of cacao products and confectionery are in conformance with and are operated or administered in conformity with good manufacturing practices to produce, under sanitary conditions, food for human consumption.

(b) The criteria in §§ 128c.3 through 128c.8 set forth additional standards to be applied in evaluating the methods and procedures used in the manufacture, processing, packaging, packing, or holding of cacao products and confectionery.

(c) Pertinent criteria from Part 128 of this chapter have been incorporated into §§ 128c.3 through 128c.8 to emphasize critical control points in the manufacture, processing, packaging, packing, or holding of cacao products and confectionery.

§ 128c.3 Plants and grounds.

Effective measures shall be taken to prevent contamination of products, raw materials, or packaging materials with microorganisms, chemicals, filth, or other extraneous material. This may be accomplished by separating the following operations by partition, location, air flow, enclosed systems, or other effective means:

(a) Receiving.

(b) Raw material storage.

(c) Cacao bean cleaning, roasting, cooling, cracking, and fanning.

(d) Cacao product milling, pressing, mixing, refining, conching, tempering, and molding.

(e) Pulverizing or separating of cocoa, and other dusty operations.

(f) Cacao product and confectionery processing.

(g) Portable equipment and utensil cleaning and sanitizing.

(h) Packaging and packing.

(i) Finished product storage and shipping.

§ 128c.4 Equipment and utensils.

(a) Food-contact surfaces shall be corrosion-free and made of nontoxic material that will not crack or disintegrate in normal operation and will withstand the environment of its intended use and the action of food ingredients, cleaning compounds, and sanitizing agents. All food-contact surfaces shall be maintained to prevent product contamination and shall be in compliance with section 409 of the act (21 U.S.C. 348) as it pertains to indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to prevent microbiological contamination in places where dirt or organic material might accumulate.

(c) Nonfood-contact surfaces of equipment shall be so constructed that they can be kept in a clean condition.

(d) Regulating and/or recording controls, thermometers, other temperature measuring devices, and temperature recording devices on equipment used to pasteurize raw materials or products shall be accurate and effective for their designated uses. The accuracy of temperature controlling, measuring, and recording devices on equipment used to control or prevent undesirable microbial growth in raw materials or finished products shall be within ±2° F.

(e) Each freezer and cold storage compartment used for storing or holding raw materials or products capable of supporting growth of micro-organisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show accurately the temperature within the compartment, and should be fitted with an automatic control for regulating temperature or an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Cooling tunnels on processing lines shall have access doors or other provisions to permit cleaning of the interior.

§ 128c.5 Personnel sanitation facilities.

(a) Adequate and readily accessible hand washing and sanitizing facilities shall be provided in the plant for employees who may handle unprotected food, unprotected packaging materials, and food-contact surfaces. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, refuse receptacles constructed and maintained in a manner to prevent product contamination. These facilities should also be equipped with water control valves so designed and constructed as to prevent recontamination of clean, sanitized hands.

(b) Readily understandable signs directing employees handling unprotected food, unprotected packaging materials, or food-contact surfaces, to wash and sanitize their hands before starting work, after each absence from post of duty, and when their hands may have become soiled or contaminated shall be conspicuously posted in the processing room(s) and in all other areas where employees may handle such materials and surfaces.

(c) Management shall maintain sufficient control to ensure that employees handling unprotected food, unprotected packaging materials, or food-contact surfaces wash and sanitize their hands before starting work, after each absence from post of duty, and when their hands may have become soiled or contaminated.

§ 128c.6 Equipment and utensil cleaning and sanitizing.

(a) Cleaning and sanitizing of utensils and equipment shall be carried out in such a manner as to prevent raw material, packaging material, or product contamination.

(b) Food-contact surfaces of equipment used for processing or holding low moisture raw materials or products such as chocolate, fats and oils, liquid nutritive sweeteners, peanut butter, and similar materials which are not conducive to microbial growth shall be maintained in a sanitary condition. When wet cleaning of such equipment may cause conditions conducive to microbial growth, other appropriate cleaning methods shall be utilized to prevent product contamination.

(c) Poisonous or dangerous cleaning compounds, sanitizing agents, and pesticide chemicals shall be applied, stored, and held in such a manner as to prevent food or packaging material contamination. These materials shall be identified and used only in such manner and under such conditions as will be safe for their intended use. Any applicable regulations promulgated by the Environmental Protection Agency for the application, use, or holding of such materials shall be followed.

§ 128c.7 Processes and controls.

The manufacturer shall employ appropriate quality control procedures and treatments to ensure that raw materials and finished products are wholesome and fit for food, that packaging materials are safe and suitable, and that all of the foregoing materials are otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.

(a) *Handling of raw materials.* (1) Milk and milk products shall have been pasteurized before use, and egg products shall have been pasteurized or otherwise treated to destroy viable Salmonella microorganisms before use, or these materials (i.e., milk, milk products and egg products) shall be pasteurized or otherwise treated during processing operations to destroy pathogenic microorganisms. The manufacturer shall ensure that gelatin, dried coconut, nuts, and other raw materials susceptible to contamination by pathogenic microorganisms are free of such microorganisms before these materials are incorporated into finished products unless these materials are pasteurized or otherwise treated before or during processing operations to destroy pathogenic microorganisms. Compliance with this requirement may be accomplished by purchasing these materials under a supplier's guarantee or certification, or verified by analyzing these materials for pathogenic microorganisms.

(2) The manufacturer shall ensure that peanuts, Brazil nuts, pistachio nuts, filberts, walnuts, almonds, pecans, corn meal, and other raw materials susceptible to aflatoxin contamination comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials are incorporated into finished products. Compliance with this requirement may be accomplished by purchasing these materials under a supplier's guarantee or certification, or verified by analyzing these materials for aflatoxins.

(3) The manufacturer shall ensure that nuts, raisins, cacao beans, spices, rework, return, and other raw materials susceptible to infestation or contamination by animals, birds, vermin, microorganisms, or extraneous material comply with current Food and Drug Administration regulations, guidelines, and action levels for natural or unavoidable defects before these materials are incorporated into finished products. Compliance with this requirement may be verified by examining these materials for infestation and contamination.

(b) *Storing and holding of raw materials.* Raw materials shall be held in containers so designed and constructed as to prevent raw material contamination. Raw materials and packaging materials shall be held at such temperature and relative humidity and in such a manner as to prevent their adulteration due to contamination or decomposition.

(1) Materials capable of supporting growth of pathogenic microorganisms shall be stored at a temperature below 40° F. or above 140° F., except for such period of time actually required for the processing involved and which does not affect the wholesomeness of the raw materials.

(2) Frozen materials shall be kept frozen and should be stored at a temperature of 0° F. or below.

(3) Liquid sugars shall be held in such a manner as to prevent microbial growth or any other direct or indirect contamination. Storage tanks for liquid sugars shall have filtered air-intake vents.

(4) Liquid mixtures containing egg products or other perishable materials and capable of supporting growth of pathogenic microorganisms shall be held in such a manner as to preclude the growth of these microorganisms or shall be processed in such a manner as to destroy these microorganisms. This may be accomplished by:

(i) Maintaining the mixtures at a temperature below 40° F. after removal from storage and disposing of the unused portion at least every 12 hours during operations and at the end of the day's operation; or

(ii) Maintaining the mixtures at a temperature below 50° F. after removal from storage and disposing of the unused portion at least every 4 hours during operations and at the end of the day's operation; or

(iii) Pasteurizing or otherwise treating the mixtures during processing operations to destroy pathogenic microorganisms.

(c) *Processing operations.* (1) Frozen egg products shall be defrosted in a sanitary manner and by such methods that their wholesomeness is not adversely affected. This may be accomplished by defrosting at a temperature of 40° F. or below, or by defrosting at a temperature above 40° F. for a period of time not exceeding 24 hours: Provided, That the temperature in any part of the defrosted liquid does not exceed 50° F.

(2) Processes intended to pasteurize or otherwise treat materials to destroy pathogenic microorganisms shall be scientifically determined to be adequate under the conditions of manufacture for a given product to ensure destruction of such microorganisms.

(3) Rework and return shall be considered as raw materials. They shall be held in properly identified containers in a manner to prevent product contamination.

(4) Waste shall not contribute to direct or indirect product contamination. This may be accomplished by holding the waste in properly identified containers and removing it from the processing area daily.

(5) Effective measures shall be taken to prevent cross contamination between raw materials and finished products or between refuse and these materials. When any of these materials are unprotected they shall not be handled simultaneously in a receiving, loading, or shipping area. Raw materials and products transported by conveyor shall be protected against contamination from extraneous material.

(6) Equipment, containers, and utensils used to convey, process, hold or store raw materials or products shall be handled during processing or storage in such a manner as to prevent raw material or product contamination.

(7) Effective measures shall be taken to prevent the inclusion of metal or other extraneous material in finished products. This may be accomplished by using suitable equipment such as sieves, magnets, electronic metal detectors, or by other effective means.

(8) Effective measures shall be taken to remove extraneous material from molding starch before it is reused in molding operations. This may be accomplished by passing the starch through a sieve and a metal trap or by otherwise treating it to remove extraneous material.

(9) The cooling and winnowing of roasted cacao beans and the processing and storage of cocoa nibs shall be carried out in such a manner as to prevent product contamination.

(10) Cacao bean shell, dust, and other residue particles resulting from cracking operations shall be handled and held in such a manner as to prevent product contamination.

(11) Adulterated materials shall be disposed of in such a manner as to prevent raw material, rework, return, or finished product contamination, or shall be reconditioned, if feasible, and then reexamined and found to be wholesome before being incorporated into finished products.

(d) *Coding.* Permanently legible code marks shall be placed at a readily visible location on each shipping container or they shall be placed on each finished product package delivered or displayed to retail purchasers and be visible on the unopened package. The code marks may be placed in both locations if desired by the manufacturer. Such marks shall identify at least the plant where packed and the product lot or packaging lot.

(e) *Warehousing and distribution.* Finished products shall be handled in storage, during shipment, and while being held for sale in such a manner as to prevent product contamination. Transportation equipment, warehouses, and other facilities used for storing, holding, or transporting finished products shall be of such design and construction as to prevent contamination or adultera-

tion of the products. Such facilities and equipment shall be free of vermin or other objectionable conditions.

§ 128c.8 Records.

(a) Records shall be maintained of the results of examinations of raw materials, packaging materials, and finished products. Suppliers' guarantees or certifications that verify compliance with Food and Drug Administration regulations and guidelines shall be retained.

(b) Processing and production records covering processes intended to pasteurize or otherwise treat materials to destroy pathogenic microorganisms shall be maintained, and shall contain sufficient information to permit a public health evaluation of the processes.

(c) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for their intended use.

(d) The records required by paragraphs (a), (b), and (c) of this section shall be retained for a period of time that exceeds the shelf life of the finished product, except that they need not be retained more than 2 years.

Effective date. This order shall be effective August 4, 1975, except that it shall become effective on December 1, 1975, where an extension is granted because of significant problems related to the supply and installation of equipment or facilities.

(Secs. 402(a)(4), 409, 701(a), 52 Stat. 1046, 1055, 72 Stat. 1785–1788 (21 U.S.C. 342(a)(4), 348, 371(a)))

Dated: May 17, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

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