certified *B. subtilis* HV1 systems: pUB110, pC194, pS194, pSA2100, pE194, pT127, pUB112, pC221, pC223.

'HV2—The following sterile strains of *Saccharomyces cerevisiae*, all of which have the ste-VC9 mutation, SHY1, SHY2, SHY3, and SHY4. The following plasmids are certified for use: YIp1, YEp2, YEp4, YIp5, YEp6, YRp7, YEp20, YEp21, YEp24, YIp25, YIp26, YIp27, YIp28, YIp29, YIp30, YIp31, YIp32, and YIp33. These plasmids can be considered EK2 vectors when propagated in chi-1776.

Appendix E

As noted in the subsections of Section IV-E-1-b-(1) the Director, NIH, may take certain actions with regard to the Guidelines after public notice and RAC consideration.

Some of the actions taken to date include the following:

• The following experiment has been approved: The cloning in *B. subtilis*, under P2 conditions, of DNA derived from *Saccharomyces cerevisiae* using EK2 plasmid vectors provided that an HV1 *B. subtilis* host is used.

• Unmodified laboratory strains of *Neurospora crassa* can be used in all experiments for which HV1 *N. crassa* systems are approved provided that these are carried out at physical containment one level higher than required for HV1. However, if P3 containment is specified for HV1 *N. crassa*, this level is considered adequate for unmodified *N. crassa*. For P2 physical containment, special care must be exercised to prevent aerial dispersal of macroconidia, including the use of a biological safety cabinet.

• P2 physical containment shall be used for DNA recombinants produced between members of the genera *Streptomyces* and *Micromonospora* except for those species which are known to be pathogenic for man, animals or plants.[2A].

• Cloned desired fragments from any non-prohibited source may be tranferred into *Agrobacterium tumefaciens* containing a Ti plasmid (or derivatives thereof), using a nonconjugative *E. coli* plasmid vector coupled to a fragment of the Ti plasmid and/or the origin of replication of an *Agrobacterium* plasmid, under containment conditions one step higher than would be required for the desired DNA in HV1 systems (i.e. one step higher physical containment than that specified in the subsections of Section III-A). Transfer into plant parts or cells in culture would be permitted at the same containment level (one step higher).

• *Bacillus subtilis* strains that do not carry an asporogenic mutation can be used as hosts specifically for the cloning of DNA derived from *E. coli* K-12 and *Streptomyces coelicolor* using NIH-approved *Staphylococcus aureus* plasmids as vectors under P2 conditions.

• *Streptomyces coelicolor* can be used as a host for the cloning of DNA derived from *B. subtilis*, *E. Coli* K-12, or from *S. aureus* vectors that have been approved for use in *B. subtilis* under P2 conditions.

• Certain cloned segments of *Anabena* DNA may be transferred into *Klebsiella* under P2 physical containment.

• Permission is granted to clone foot-and-mouth disease virus in the EK1CV host-vector system consisting of *E. coli K-12 and the vector pBR322, all work to be done at the Plum Island Animal Disease Center.*

Dated: January 23, 1980.

Donald S. Fredrickson,

Director, National Institutes of Health.

[FR Doc. 80-2822 Filed 1-28-80; 8:45 am]

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federal register

Tuesday
January 29, 1980

Part VII

Environmental Protection Agency

Authorization of State Hazardous Waste Programs; Advance Notice of Final Regulation

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 123

[FRL 1396-6]

Authorization of State Hazardous Waste Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance Notice of Final Regulation.

SUMMARY: EPA today is giving notice of the requirements it intends to promulgate for interim and final authorization of State hazardous waste programs under Section 3006 of the Resource Conservation and Recovery Act of 1976, as amended (RCRA). The purpose of this notice is to provide advance guidance to States to give them full opportunity to qualify for interim authorization by the effective date of the first phase of the Federal program. This notice should also assist States in developing an authorization plan to describe how a State will develop a program capable of receiving final authorization.

DATE: A meeting to brief State officials and the public on this notice will be held on February 12, 1980 at 1:30 p.m.

ADDRESS: Room 3906, EPA Headquarters, 401 M Street, S.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Region I

Dennis Huebner, Chief, Radiation, Noise, and Solid Waste Branch, John F. Kennedy Building, Boston, Massachusetts 02203, (617) 223-5708.

Region II

Dr. Ernest Regna, Chief, Solid Waste Branch, 26 Federal Plaza, New York, New York 10007, (212) 264-0503/4/5.

Region III

Robert L. Allen, Chief, Hazardous Materials Branch, 6th & Walnut Streets, Philadelphia, Pennsylvania 19106, (215) 597-0980.

Region IV

James Scarbrough, Chief, Residuals Management Branch, 345 Courtland Street NE., Atlanta, Georgia 30308, (404) 881-3016.

Region V

Karl J. Klepitach, Jr., Chief, Waste Management Branch, 230 South Dearborn Street, Chicago, Illinois 60604, (312) 866-6148.

Region VI

Dr. Richard Hill, Chief, Solid Waste Branch, 1201 Elm Street, First International Building, Dallas, Texas 75270, (214) 767-2645.

Region VII

Robert L. Morby, Chief, Hazardous Materials Branch, 324 E. 11th Street, Kansas City, Missouri 64106, (816) 374-3307.

Region VIII

Lawrence P. Gazda, Chief, Waste Management Branch, 1860 Lincoln Street, Denver, Colorado 80203, (303) 837-2221.

Region IX

Robert Kuykendall, Chief, Hazardous Materials Branch, 215 Fremont Street, San Francisco, California 94105, (415) 556-4606.

Region X

Kenneth D. Feigner, Chief, Waste Management Branch, 1200 6th Avenue, Seattle, Washington 98101, (206) 442-1260.

Headquarters

Sam Morekas, U.S. Environmental Protection Agency, Office of Solid Waste (WH-563), Washington, D.C. 20460, (202) 755-9145.

SUPPLEMENTARY INFORMATION:

Executive Summary

In the next few months EPA will be issuing final regulations to control the management of hazardous wastes. These regulations will establish a Federal regulatory program that will ensure that hazardous wastes are transported, stored, treated and disposed of in a manner that protects public health and the environment.

The first phase or "core" of the Federal program is expected to be published by April 1980 and will be in effect in October 1980. Then, generators and transporters of hazardous waste will have to comply with the Section 3002 and Section 3003 regulations, including the use of a manifest system. Owners and operators of treatment, storage and disposal facilities will have to meet the first set of standards set forth in the Section 3004 regulation.

As soon as practicable after April 1980, EPA will promulgate the remaining parts of the Section 3004 regulation which will set forth additional technical standards for treatment, storage and disposal facilities. The second phase of the Federal progam, which involves the issuance of permits for such facilities, will then begin.

RCRA allows EPA to grant final authorization to States to carry out hazardous waste management programs which are equivalent to the Federal program. EPA may also grant States interim authorization for a period of two years to carry out substantially equivalent hazardous waste programs. The period of interim authorization is intended to provide States with time to develop programs so that they become capable of receiving final authorization.

The purpose of this notice is to provide advance guidance to States to give them full opportunity to qualify for interim authorization by the effective date of the first phase of the Federal program. This notice should also assist States in developing an authorization plan to describe how a state will develop a program capable of receiving final authorization.

Final Authorization

Appendix A outlines the major features of the minimum requirements for final authorization. Additional and more specific information will be provided in the EPA regulations to be issued on this subject in April of this year.

In summary the requirements for final authorization are that the State demonstrate that its program:

1. Assures control over the same universe of hazardous wastes and the same population of generators, transporters and hazardous waste (treatment, storage and disposal) facilities as the Federal program.

2. Requires that generators, transporters and hazardous waste facilities comply with standards that are equivalent (or equal in effect) to the Federal standards.

3. Requires that generators and transporters of hazardous wastes use a manifest system that ensures shipments of hazardous waste are only delivered to authorized facilities. The State manifest system must adopt certain aspects of the Federal manifest system in order that intrastate and interstate shipments of hazardous waste are managed in a consistent manner nationwide.

4. Requires a permit for all hazardous waste storage, treatment and disposal facilities. This permit program must be administered through procedures that are equivalent to the Federal program.

Since the criteria for final authorization depend on the complete set of Federal regulations, final authorization of State programs cannot begin until the effective date of the second phase of the Federal program.

Interim Authorization

In establishing the requirements for interim authorization EPA had to balance a number of somewhat competing interests, including the desire to promote uniform State programs as quickly as possible and the desire not to disrupt existing State efforts through the imposition of separate and parallel Federal requirements. The Agency also had to recognize that the Federal program would become effective in two phases and would continue to expand and evolve over time. Appendix B explains the logic used in dealing with

this complex issue and outlines the basic requirements for interim authorization.

RCRA states that in order to receive interim authorization a State program must be substantially equivalent to the Federal program. In summary this is interpreted to mean that the State demonstrate that its program:

1. Controls a nearly identical universe of hazardous wastes generated, transported, treated, stored and disposed of in the State as would be controlled by the Federal program.

2. Covers all types of hazardous waste management facilities existing in the State as of the date of interim authorization.

3. Is based on standards that provide substantially the same degree of human health and environmental protection as the Federal standards and is administered through procedures that are substantially equivalent to the procedures used in the Federal program.

A State program will have the opportunity to receive interim authorization in phases similar to the implementation of the Federal program.

If a State program meets all of the other requirements for interim authorization except that it does not have a manifest system to control shipments of hazardous waste, the State may receive interim authorization for the remainder of the program and the Federal manifest system will be administered in the State by EPA.

Finally, in order to receive interim authorization, a State must have an authorization plan that commits the State to closing the gaps in its existing program as soon as practicable and to developing a program capable of receiving final authorization by the end of the interim authorization period. The State/EPA Agreement should reflect this commitment, delineate State and EPA responsibilities during the interim authorization period, and clearly communicate this information to the public.

Other State-EPA Relationships

EPA contemplates providing those States which do not qualify for interim authorization the opportunity to enter into cooperative arrangements with EPA under which they would be responsible for administering portions of the Federal hazardous waste program until they are authorized to run the State program, and with financial support through the Subtitle C grant program under Section 3011. Guidance on this approach to cooperation between EPA and the States will be issued within 30 days.

* * * * *

In order to assist the States better to understand these policies, EPA will hold a briefing on this notice for State representatives on February 12 1980, at 1:30 p.m. in Room 3906, EPA Headquarters, 401 M Street, S.W., Washington, D.C. this briefing will be open to the public.

Dated: January 24, 1980.

Douglas M. Costle,

Administrator.

Appendix A—Requirements for Final Authorization

Under RCRA, before the Administrator can approve final authorization for a State program he must find that it (1) is "equivalent" to the Federal program, (2) is "consistent" with the Federal program and programs in authorized States, (3) provides "adequate enforcement" and (4) provides adequate public participation. (Requirements 1, 2 and 3 are found in Section 3006(b); requirement 4 is derived from Section 7004(b)).

EPA interprets the term equivalent to mean "equal in effect." EPA has used this interpretation of equivalence in establishing minimum requirements for final authorization of State programs. Each requirement of the Federal program has been analyzed to determine the minimum a State must do to meet the four statutory criteria of equivalency, consistency, enforceability and public participation. In some instances EPA has concluded that the requirements for States must be very similar to the Federal program requirements in order to be equal in effect. In other instances the State may adopt standards which it demonstrates to be at least equal in effect to the Federal standards in the area. The more closely the State standard resembles the Federal standard, of course, the easier the determination that it is equal in effect.

In evaluating State programs for final authorization, one of EPA's primary concerns will be whether the State program controls, at a minimum, the same universe of hazardous wastes and the same generators, transporters and hazardous waste facilities as the Federal program. One way of assuring this would be for the State program to adopt the hazardous waste characteristics and lists promulgated by EPA under Section 3001 and certain definitions and other provisions of the Federal regulations.

The consistency criterion is very important with respect to the manifest system, which is applicable to both intrastate and interstate shipments of hazardous waste nationwide. The Agency believes that a State must adopt certain aspects of the Federal manifest system in order for the State program to be consistent with the Federal program and other State programs. Also, in order for a State program to be consistent with other programs, no aspect of that program should restrict or impede the free movement of hazardous waste across State borders to permitted facilities.

Following is an outline of the major features of the minimum requirements for final authorization. In order to receive final authorization a State program must meet the requirements of 40 CFR Part 123 (the consolidated permit regulations) which will be promulgated in April. More specific requirements will, of course, be provided in these regulations, as will EPA's statement of basis and purpose and response to comments.

A. General

The State program must demonstrate control over the same universe of hazardous waste, generators, transporters and treatment, storage and disposal facilities covered by the Section 3001–3005 regulations and must assure that this control continues as the scope of the Federal program expands in the future.

Specifically, the State program must demonstrate:

1. Legislative authority adequate for the State to carry out its responsibilities;

2. Regulations in effect necessary to implement the requirements of the program;

3. The capacity to inspect, monitor, and require of the regulated community recordkeeping, reporting and monitoring in order to determine compliance with the requirements of the program, and to obtain information necessary to meet EPA requirements for State reporting (as will be described in the final consolidated permit regulations);

4. Enforcement capabilities that are adequate to ensure compliance with the requirements of the program (More specific requirements for enforcement capabilities will be provided in the final consolidated permit regulations); and

5. Adequate resources to administer and enforce the requirements of the program.

B. Generator and Transportation Standards

1. The State program must demonstrate that generators and transporters of hazardous waste use a manifest system that ensures that interstate and intrastate shipments of hazardous waste are delivered only to

facilities that are authorized to operate under RCRA.

2. Requirements for the State manifest system are:

(a) The EPA identification code must be used to identify generators, transporters and facilities.

(b) The Federal manifest format must be used (but may be supplemented to a limited extent subject to U.S. Department of Transportation (DOT) constraints).

(c) All wastes transported to an off-site facility must be accompanied by a manifest.

(d) The generator must initiate the manifest and designate the storage, treatment, or disposal facility to which the waste is to be shipped.

(e) The transporter must carry the manifest and deliver wastes only to that designated facility.

(f) The facility owner/operator must return a copy of the manifest to the generator indicating delivery of the waste shipment.

(g) The generator must be responsible for investigating unreturned manifests and reporting undelivered shipments to the State.

(h) For interstate shipments, the State program must provide for notification to other States (or EPA in unauthorized States) of undelivered shipments.

3. For hazardous wastes that are discharged (spilled) in transit, the State program must require that transporters clean up such wastes or take action so that such wastes do not present a hazard to human health or the environment. Transporters must be required to notify appropriate State, local and Federal agencies of such discharges.

4. For hazardous wastes that are accumulated for short periods of time prior to shipment off-site, the State program must require that generators accumulate such wastes in containers meeting DOT shipping requirements or be stored in accordance with authorized State storage standards.

5. The State program must require that generators and transporters comply with requirements for the labeling, marking, placarding and containerization of hazardous wastes that are equivalent to the requirements of the Section 3002 and 3003 regulations.

C. Facility Standards and Permit Program

(1) The State program must demonstrate that hazardous waste storage, treatment and dispoal facilities comply with standards that provide the same degree of human health and environmental protection as the standards promulgated in the Section 3004 regulations.

(2) The State standards for treatment, storage and disposal facilities must cover (as a minimum):

(a) Technical standards for tanks, containers, basins, waste piles, incineration, chemical physical and biological treatment, surface impoundments, landfills and land treatment facilities;

(b) Financial responsibility (insurance) during facility operation;

(c) Preparedness for and prevention of discharges of hazardous waste, and contingency plans and emergency procedures to be followed in the event of a discharge of hazardous wastes;

(d) Closure and post-closure requirements, including financial requirements for closure and post-closure monitoring and maintenance;

(e) Groundwater monitoring;

(f) Security to prevent unauthorized access to the facility;

(g) Facility personnel training;

(h) Inspections, monitoring, recordkeeping and reporting;

(i) Compliance with the manifest system by storage, treatment, and disposal facilities; and

(j) Other aspects to the extent that they are included in the Section 3004 regulation.

(3) The State program must require a permit for all hazardous waste storage, treatment and disposal facilities for which a permit is required by Section 3005 and the Section 3005 regulations. The State program must prohibit the operation of such facilities except as authorized by a State permit program. The State permit may be issued only to facilities that comply with authorized State standards.

(4) The State permit program must be administered through procedures that are equivalent to the procedures for the Federal permit program described in Section 3005 regulation. (More specific requirements for State permit program procedures will be included in the final consolidated permit regulations.)

Since the criteria for final authorization depend on the Federal regulations, final authorization of State programs cannot begin until the effective date of the Phase II Section 3004 regulation which will set forth technical standards for permitting storage, treatment and disposal facilities.

Appendix B—Requirements for Interim Authorization

RCRA specifies in Section 3006(c) that in order to receive interim authorization, a State program must be "substantially equivalent" to the Federal program. The Agency interprets substantial equivalence as "to a large degree or in the main, equal in effect."

Substantial Equivalence

As the result of a recent analysis of State legislation and regulations, three areas have been identified where this definition of substantial equivalence must be clarified.

First, the part of the Federal program for which States will now have the most difficulty in meeting the substantial equivalence test is the generator and transporter standards; in particular, many States probably will not have a manifest system in place that adequately controls interstate shipments of hazardous waste and is consistent with the Federal manifest system. The Agency does not believe that the lack of authority for this program part should cause States to be denied interim authorization. Such a decision would result in parallel Federal and State programs in many States with attendant duplicative regulation and resource expenditures. On the other hand, the manifest system is the heart of the "cradle-to-grave" control system of RCRA and has significant consequences on interstate commerce. Accordingly, EPA will administer and enforce the Federal manifest system and generator and transporter requirements if the State lacks the necessary legal authority.

Second, present State laws and regulations define hazardous wastes in ways which make it likely that few if any States now cover exactly the wastes which will be identified in the Section 3001 regulation. Time will be needed to bring the State definitions into conformance with the Federal definition. Accordingly, State procedures for defining hazardous wastes will be compared to the Section 3001 regulation, and differences will be identified. The requirement will be that the State program control as nearly identical a universe of hazardous wastes generated, transported, treated, stored or disposed of in the State as would be controlled by the Federal program. While some exceptions to the Federal universe may be allowed, this must not create a significant loophole that would exempt entire classes of wastes or practices from adequate control. For these reasons, only relatively minor differences between the Federal and State definitions of hazardous wastes will be allowed during interim authorization.

Third, some States do not have regulatory authority over all types of hazardous waste facilities. Generally these are facilities which do not exist in the State. The only types of hazardous

waste management facilities a State need not have authority to regulate during interim authorization will be those types of facilities which do not exist in the State as of the date of interim authorization.

The State authorization plan must provide for closing all of the legislative and regulatory gaps in the State hazardous waste program as soon as practicable and in no event later than the end of the interim authorization period.

Phasing of Interim Authorization

As mentioned previously, EPA will be issuing the Section 3004 regulation in two major phases. Therefore interim authorization will be divided into two phases which correspond to the two Federal regulation phases. Phase I will cover generator and transporter requirements and preliminary facility standards. Phase II will cover permitting of hazardous waste treatment, storage and disposal facilities.

The two phases are considered to be integral parts of a complete State hazardous waste program; EPA does not intend to provide authorization for only one phase since it views interim authorization as a stage leading towards full authorization.

States may receive interim authorization for Phase I beginning on the effective date of the initial Section 3001–3005 regulations. States may receive interim authorization for Phase II after thePhase II Section 3004 regulation is promulgated. In order to give States the two-year period of time that Congress intended be available to them to develop final programs, interim authorization for both phases will be allowed to continue for 24 months from the effective date of the Phase II Section 3004 regulation. At the end of this period, all interim authorizations will automatically expire and EPA will administer the Federal program in any State which has not received final authorization.

Following is an outline of the major features of the requirements for interim authorization. In order to receive interim authorization a State must meet the requirements of 40 CFR Part 123. More specific requirements will, of course, be provided in that part of the consolidated permit regulations, as will EPA's statement of basis and purpose and response to comments.

A. General

The State program must demonstrate control over as nearly identical a universe of hazardous wastes (as defined by the Section 3001 regulation) generated, transported, treated, stored and disposed of in the State as would be controlled by the Federal program. The authorization plan must delineate actions the State will take to control the complete universe of hazardous wastes as soon as practicable.

In general, in order to receive interim authorization for either phase, a State program must demonstrate:

(1) Legislative authority adequate for the State to carry out its responsibilities for that phase

(2) Regulations in effect necessary to implement the requirements of that phase

(3) The capacity to inspect, monitor, and require of the regulated community recordkeeping, reporting and monitoring in order to determine compliance with the requirements of that phase of the program and to obtain information necessary to meet EPA requirements for State reporting (as will be described in the final consolidated permit regulations)

(4) Enforcement capabilities that are adequate to ensure compliance with the requirements of that phase

(5) Adequate resources to administer and enforce the requirements of that phase of the program and

(6) An authorization plan describing the additions and modifications that will be made to the State program in order to qualify for final authorization by the end of the interim authorization period.

There are a few exceptions to these requirements which are discussed below.

B. Specific Criteria for Phase I

1. Preliminary Facility Standards. The State program must require that hazardous waste treatment, storage and disposal facilities comply with standards that provide substantially the same degree of human health and environmental protection as the facility standards promulgated in the Phase I, Section 3004 regulation. The State program must prohibit the operation of facilities that are not in compliance with these State standards. The State standards for treatment, storage and disposal facilities should cover:

(a) Preparedness for and prevention of discharges of hazardous waste, and contingency plans and emergency procedures to be followed in the event of a discharge of hazardous waste

(b) Closure and post-closure requirements, including financial requirements for closure and post-closure monitoring and maintenance

(c) Groundwater monitoring

(d) Security to prevent unauthorized access to the facility

(e) Facility personnel training

(f) Inspection, monitoring, recordkeeping and reporting

(g) Compliance with the manifest system (see 2(b)(iii) below)

(h) Other facility standards to the extent that they are included in the Phase I Section 3004 regulation

2. *Generator and Transporter Standards.* (a) The State program must require that generators and transporters of hazardous waste use a manifest system that ensures that interstate and intrastate shipments of hazardous waste are delivered only to facilities that are authorized to operate under RCRA.

(b) The State manifest system must require that:

(i) The manifest identify the generator, transporter, facility, and the waste being shipped

(ii) Copies of the manifest are carried with all hazardous waste shipments

(iii) shipments of hazardous waste that are not delivered to a designated facility are identified and reported by the generator to the State (or identified by the State)

(iv) For all shipments received from another State, the facility owner/operator or the State must return a copy of the manifest to the generator indicating delivery of the waste shipment (see l(g) above)

(c) For hazardous wastes that are discharged (spilled) in transit, the State program must require transporters to clean up such wastes or to take action so that such wastes do not present a hazard to human health or the environment. Transporters must be required to notify appropriate State, local and Federal agencies of such discharges.

(d) For hazardous wastes that are accumulated by generators for short periods of time prior to shipment, the State program must require that generators accumulate such wastes in a manner that does not present a hazard to human health or the environment.

During the interim authorization period a State which is presently operating a manifest system need not have a system identical to the Federal manifest system, provided the system can operate as part of the national system. The intent is to allow States with existing manifest systems adequate time to modify such systems to make them consistent with the Federal system. All States should make such modifications as quickly as possible, especially for interstate shipments of hazardous waste. On the other hand, all States developing new manifest systems must insure that they are equivalent and consistent with the Federal system as required for final authorization.

If a State meets all of the other requirements for interim authorization for Phase I except that it does not have legislative authority or regulations for the manifest system and other generator and transporter requirements discussed above, the State may be granted interim authorization for the remainder of Phase I, providing the State authorization plan delineates the necessary steps for obtaining such legal authority or regulations as soon as practicable. Until such State requirements are approved, Federal requirements for generators and transporters will apply in such States (including the use of the Federal manifest system), and enforcement responsibility for that part of the program will remain with the Federal Government.

If a State does not have legislative authority or regulatory control over certain activities that do not occur in the State, the State may be granted interim authorization for Phase I providing the State authorization plan provides for the development of a complete program as soon as practicable after receiving interim authorization.

C. Specific Criteria for Phase II—Facility Permitting

(a) The State program must require that hazardous waste treatment, storage and disposal facilities comply with standards that provide substantially the same degree of human health and environmental protection as the standards promulgated in the final Section 3004 regulation.

(b) The State program must require a permit for all hazardous waste treatment, storage and disposal facilities which handle any waste considered hazardous under the Phase I program and for which a permit is required by Section 3005 and the Section 3006 regulations. The State program must prohibit the operation of such facilities except as authorized by a State permit.

(c) The State permit program should be administered through procedures that are substantially equivalent to the procedures for the Federal permit program described in the Section 3005 regulation especially with respect to public participation in the permitting process.

As stated earlier, EPA does not intend to provide authorization for only one phase. If a State has been granted interim authorization for Phase I, but does not receive interim authorization for Phase II by the effective date of the Federal permit program, the State program could continue to be authroized for Phase I provided the State authorization plan describes the steps that will be taken to meet the criteria for Phase II authorization as soon as practicable. During the period for which a State was not authorized for Phase II, EPA could administer the Federal permit program in the State.

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federal register

Tuesday
January 29, 1980

Part VIII

Department of Agriculture

Food and Nutrition Service

National School Lunch Program and School Breakfast Program; Competitive Foods

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210 and 220

[Amdt. No. 37 for Part 210; Amdt. No. 32 for Part 220]

National School Lunch Program and School Breakfast Program; Competitive Foods

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations for Part 210, National School Lunch Program, and Part 220, School Breakfast Program, to implement the amendment of section 10 of the Child Nutrition Act of 1966 by section 17 of Public Law 95–166, respecting the sale of foods in competition with meals served under the National School Lunch Program and the School Breakfast Program. Specifically, this final rule restricts the sale of categories of foods of minimal nutritional value from the beginning of the school day to the end of the last lunch period. Foods of minimal nutritional value are defined as those foods which provide less than 5% of the USRDA for each of eight specified nutrients per 100 calories *and* per serving. For example, licorice does not contain even 5% of the USRDA for any one of the eight specified nutrients per 100 calories or per average serving. In the case of artificially sweetened foods, only the per serving measure will apply. The restricted categories of foods are identified in Appendix B as soda water (carbonated beverages), water ices, chewing gum, and certain candies (hard candies, jellies and gums, marshmallow candies, fondants, licorice, spun candies, and candy coated popcorn). This rule affects only those schools participating in the National School Lunch and School Breakfast Programs.

DATES: Effective January 29, 1980.

Implementation date: July 1, 1980. The Department encourages schools to work towards the July 1 implementation date of this final rule by phasing out the foods of minimal nutritional value at this time. (For more information read Section IV. D.)

FOR FURTHER INFORMATION CONTACT: Stanley C. Garnett, Branch Chief, (202) 447–9069, School Programs Division, USDA, FNS, Washington, D.C. 20250.

SUPPLEMENTARY INFORMATION:

Table of Contents of Preamble

I. Introduction

Congress has placed responsibility for administration of the School Breakfast Program and the National School Lunch Program in the Department of Agriculture. In carrying out this responsibility we have established minimum standards for foods served by local School Food Authorities wishing to participate in the federal school food programs. These standards, such as the meal pattern requirements for school lunches, are imposed as conditions of receiving federal funds and are designed to ensure that those funds are used to promote good nutrition among students.

In 1977, Congress enacted the competitive foods amendment to the Child Nutrition Act of 1966. That amendment authorized the Secretary to regulate the sale of foods in competition with meals served in the School Breakfast and National School Lunch Programs in participating schools. This final rule establishes minimum nutritional standards for such competitive foods. It identifies foods of minimal nutritional value and restricts their sale from the beginning of the school day until after the last lunch period.

A. Legislative Background From 1970 to 1977

On October 10, 1977, Congress enacted Public Law 95–166. Section 17 of that statute amended Section 10 of the Child Nutrition Act of 1966 to restore to the Secretary of Agriculture the authority to regulate the sale of competitive foods in schools participating in the National School Lunch and/or the School Breakfast Programs. This rulemaking proceeding was initiated to implement this competitive foods amendment. Competitive foods are any foods sold in competition with the National School Lunch or School Breakfast programs.

Prior to 1977, the sale of competitive foods in schools had twice engaged the attention of Congress. In 1970, the concerns of numerous public organizations and local governments about the increasing variety and quantity of foods being sold in competition with the school feeding programs led to the first competitive foods amendment to Section 10 of the Child Nutrition Act of 1966 (Pub. L. 91–248).

This amendment provided statutory authority to the Secretary of Agriculture to regulate foods sold in competition with the nonprofit school feeding programs authorized under the Child Nutrition Act and the National School Lunch Act. Regulations implementing the 1970 amendment allowed the competitive sale of only those foods which either fulfilled a requirement of the prescribed meal pattern for school lunches or were served along with such a lunch.[1] Thus, the effect of the 1970 rule was to allow any food served as part of a school lunch also to be sold competitively. For example, under this rule, if a school sometimes served cake as dessert with the meal, cake could then be sold as a competitive food. Because of wide local discretion in the choice of foods served, the result of this rule in many places was that only soft drinks and some candies—which were rarely served along with the school meals—were disallowed.

While the impact of the 1970 rule was thus limited, it nonetheless aroused controversy, and some groups advocated the transfer of the Secretary's authority to regulate competitive foods to State and local education agencies.

Section 10 was again amended in 1972 by Pub. L. 92–433. The 1972 amendment restricted the Secretary's regulatory powers under the statute by providing that federal regulations could not prohibit the sale of competitive foods if the proceeds of such sale accrued to the schools or approved student organizations. Thus, the 1972 amendment placed authority for the regulation of competitive foods with State agencies and local School Food Authorities. Various types of competitive foods rules were developed by State and local bodies in the years that followed. During this period the States were free, as they always have been, to adopt regulations which placed greater restrictions on the sale of competitive foods than the federal rule required.

Nationwide, the regulation of the sale of competitive foods under the 1972 amendment was unsystematic. Foods approved for competitive sale varied among localities, and many jurisdictions developed no competitive foods regulation at all. By 1977, owing to increasing concerns about the quality of childrens' diets, there was growing

dissatisfaction with the results of the 1972 competitive foods provision. Nutritionists, parents, school administrators, and others urged legislation restoring regulatory authority to the Secretary of Agriculture. The Department also supported such legislation.

In 1977, Congress responded by again amending Section 10 to restore to the Secretary authority to regulate the sale of competitive foods. The Department did not propose this provision in Public Law 95–166 but supported its adoption. This rule is a direct result of that amendment.

B. Background History From 1977 to Present

On April 25, 1978, the Department published a proposed rule regulating the sale of competitive foods (43 FR 17476). Over 2,100 public comments were submitted in response to this proposal. After analysis of these comments, we determined that additional consideration of the issues they raised was necessary. Accordingly, we withdrew the April 25 proposal, held a series of public meetings to discuss these issues, and solicited further written comments to aid in formulation of a new proposal.

On July 6, 1979, the Department published another proposed rule concerning competitive foods (44 FR 4004). During the public comment period which followed, 3,067 comments were received from parents, businesses, industry officials, teachers, school foodservice personnel, nutritionists, dentists, other medical professionals, and other concerned citizens.

Of the 3,067 comments received, 23% (692) were from commentors who expressed opposition to a federal rule of any kind. The other 77% (2375) of the commentors either expressed support for the proposed rule, focused on specific concerns about the proposal and/or did not state any objection to federal rulemaking on the competitive foods issue.

The majority of those commentors who opposed any federal rule (524) are listed in the comment analysis category "concerned citizen." It should be noted that in analyzing the comments, the Department categorized any comment which did not indicate a particular association (such as teacher, food service personnel, student, or industry) as a comment from a "concerned citizen."

Approximately 562 comments (20% of the total) were received which, because of their similar content and format, appeared to have been generated by PepsiCo Incorporated. A few PepsiCo employees sent the Department copies of similar form letters opposing the rule stating that PepsiCo had distributed the forms to its employees with the suggestion that the employees send them to USDA on their own letterhead.

A number of commentors again raised issues which were considered in the formulation of the July 6 proposal. The rationales for decisions made in drafting that proposed rule are fully explained in its preamble which appears at 44 FR 40004. Many of these issues are, therefore, only briefly discussed in this preamble. Those aspects of the proposal which remain unchanged in this final rule were carefully scrutinized in light of the comments in order to insure that the supporting reasons presented in the July 6 preamble remain sound.

Of the total comments received, 48.1% (1,476) stated objections to the rule or some aspect of it as proposed, while 51.3% (1,572) stated support for the entire proposal or part of it.

Of the 39 comments from State directors and State staff, 27 favored the proposed rule, 11 objected to some aspects and 1 expressed neither view. Of those who objected to some aspect of the rule, seven suggested that the establishment of a minimum standard would jeopardize more stringent existing State policies regarding the sale of competitive foods. We emphasize that State and local authorities should view this rule as a minimum standard which, like the required meal pattern, may be improved upon by State and local authorities.

Some comments from State officials as well as other school personnel expressed concern that the rule would lead students to leave the school campus in order to obtain the restricted foods. The Department believes that movement off-campus by students has multiple causes and, if it occurred, could not be directly attributed to the operation of the rule.

There were 87 comments from food service personnel. There were 36 comments opposed to the rule and 51 in favor. Of the 36 commentors who expressed some opposition to aspects of the rule, many voiced concern about fortification. This issue is discussed in detail later in this preamble. Some of the food service commentors were also concerned about the possibility that the rule would lead to increased paperwork. The Department has deliberately fashioned this rule to minimize the paperwork burden at the local, State, and regional level. For this reason, the rule restricts the sale of foods in identifiable categories rather than on an individual basis.

Of the 159 "interested organizations" comments (e.g., PTA's, food/nutrition groups), 27 stated opposition to the rule and 132 favored the rule. Of the 27 who expressed some opposition to the proposed rule, 16 opposed any federal action. Concerns raised by commentors in this category include a request that the rule be integrated with nutrition education in some manner and that it incorporate some type of parent and student involvement at the local level.

While this rule does not deal explicitly with these two concerns, other activities of the Department address these questions. The Nutrition Education and Training (NET) Program established by Congress in 1977 gives States funds to administer nutrition education programs for children. Many States and localities have used these funds for nutrition education projects on snacking habits. The Department hopes that these jurisdictions and others will include the issue of competitive foods within these educational activities. The Department has already considered the issue of parent and student involvement, but in a broader context than the competitive foods rule. In the final rule on meal pattern changes, the Department included a requirement that schools actively seek to involve parents and students in the school meals programs. The implementation of this regulation could very easily encompass involvement by students and parents in additional decisions regarding competitive foods.

In the industry category, 22 of the total 112 comments expressed support while 88 opposed the rule. Of the 88 who expressed some dissatisfaction with the rule, 55 opposed the rule because they felt there should be no federal action in this area. Some industry commentors indicated that the Department's objectives could be better achieved through nutrition education programs. The Department believes that this rule is consistent with its efforts to promote nutrition education and complements those efforts. Other commentors indicated that the definitions used in the proposed rule were confusing. The Department has attempted to clarify the definition of foods of minimal nutritional value and to use that definition consistently throughout this preamble.

Of the 450 student commentors, 225 opposed the rule, 210 favored the rule and 15 expressed no opinion. Most of the 225 who opposed the rule stated no specific reason for their opposition. Eighteen expressed concern that there would be a loss of revenue to student organizations as a result of the application of the rule. The Department

has thoroughly considered this issue which has been raised during each public comment period and at public hearings. The Department finds no conclusive evidence that the rule will necessarily lead to diminished revenues.

Of the 237 comments from medical, dental and nutritional professionals, only 13 expressed any type of opposition to the rule. Of those, roughly half thought there should be no federal rule on competition foods.

In subsequent sections of the preamble, key issues are discussed in greater detail.

II. Review of Literature

In evaluating the need for a competitive foods rule and in designing its specific features, we reviewed the scientific literature on the relation of diet to disease, the patterns of food consumption among children, and the nutritional status of children. The outcome of this review and our resulting conclusions are summarized below:

1. Numerous current studies and publications deal with associations between diet and disease and, specifically, with the health effects of the overconsumption of the food components sugar, fat and salt. A summary of the information in these studies appears in the **Federal Register** notice of December 15, 1978 at 44 FR 58780. The Department concluded on the basis of a review of these sources that a significant portion of the population has nutritional problems resulting from overconsumption and poor food choices.

These conclusions have been corroborated by more recent findings. The American Society for Clinical Nutrition provided a symposium on "The Evidence Relating Six Dietary Factors to the Nation's Health." A group of scientists studied the available evidence and reported on the strength of the associations between various dietary factors and prevalent chronic diseases. They found four correlations to be of considerable strength. The strongest association was the relationship of alcohol consumption to liver disease. The second was between sugar and dental caries. The third showed a relationship between salt and hypertension. The fourth showed a relationship between cholesterol and saturated fat and coronary disease.[2]

The Surgeon General's report, "Disease Prevention and Health Promotion: Federal Programs and Prospects," recently published with background papers prepared by the Institute of Medicine of the National Academy of Sciences, discusses associations between sucrose consumption and dental caries, between dietary fat, cholesterol and salt and cardiovascular disease, and between dietary factors and increased risk of cancer. The report terms overconsumption the key nutrition problem in the United States and recommends the reduction of calories, fat, cholesterol, sugar and salt.[3]

The National Cancer Institute presented a statement in October 1979 at Senate committee hearings on the relationship between cancer and dietary practices. The statement pointed to studies which suggest that a high fat intake may be associated with an increased risk of cancer. While the Institute acknowledged that definitive evidence is not yet available, it proposed prudent interim principles, based on evidence that is presently available. The Institute made the following recommendation: "To facilitate control of body weight, and in view of the suggestive association between fat consumption and the risk of cancer, a high intake of fat should be avoided.[4]

2. Current studies and publications dealing with nutritional status of children in the United States and with their dietary practices indicate that some children consume less that the recommended level of some nutrients. The Ten State Nutrition Survey conducted by the Department of Health, Education and Welfare (HEW) [5] reports that iron deficiency is a widespread problem in the population. Data from the Health and Nutrition Examination Survey (HANES) of HEW [6] show that intake of iron is low for a significant proportion of children aged 6–17. In the Bogalusa Heart Study,[7] a recent study of the dietary and cardiovascular status of rural school age children funded by the National Institutes of Health, at least one-third of all children studied consumed less than two-thirds of the recommended dietary allowances (RDA) of vitamin A, ascorbic acid, and niacin for their age and sex.

In addition to nutrient consumption, calorie consumption is also of concern in assessing the nutritional status of children. The Bogalusa Heart Study reported that 19% of the boys and 25% of the girls consumed less than two-thirds of the RDA for calories for their age and sex.[8] The HANES data indicated that many children consumed less than recommended levels of calories, but the report cautioned that calorie intake cannot be analyzed meaningfully unless it is related to activity and weight status.[9] Although these studies have indicated that calorie consumption among school children is at times less than the RDA's, it may be that the established standards are too high. It is widely recognized that there are significant variations in energy demands from individual to individual, particularly among children.

The most appropriate way to assess whether caloric needs are being met is to examine the physiological status of children. If there are significant levels of underweight or growth retardation, it would indicate possible caloric deficiencies. However, there are no data showing significant levels of underweight or growth inadequacy among school aged children in the United States. Physical status findings from the HANES survey and other major surveys of the growth and health of U.S. children reveal that underweight and stunted growth are not observed in a high proportion of children in the United States.[10] In fact, caloric excess leading to obesity is a greater concern than stunted growth.

The Ten State Nutrition Survey found that 9 to 39 percent of adolescents were obese.[11] There is particular concern over childhood obesity because of the likelihood that the pattern, once set, will persist into adulthood. Parental obesity and obesity during childhood appear to be major predictors of obesity in an adult. Obesity is generally regarded to be a risk factor in hypertension, heart disease and diabetes. Thus, there is substantial reason to attempt to prevent the onset of obesity in children.

These findings on the health and nutritional status of children indicate that overconsumption of calories may be a problem at the same time that nutrient intake is inadequate.

3. Studies of the food consumption patterns of children show that snacking makes a significant contribution to the total calories they consume daily. Ninety-eight percent of the children interviewed in the Bogalusa Heart Study consumed some snacks. Snacks contributed one-third (34 percent) of the daily calories in the diets of the children who snacked, more than the contribution of breakfast (17 percent of calories), lunch (23 percent of calories) or dinner (29 percent of calories). For about one-third of the Bogalusa children (30 percent), snacks contributed between 40–70 percent of their total calories. Snacks sometimes took the place of meals. For some children an almost hourly snacking pattern was apparent. Although snacks contributed *more* total calories to diets than any other single factor, they contributed *less* to nutrient levels than did meals.

Snacks provided calories mainly from fat and sucrose. In the Bogalusa study, they provided 31% of the fat and 59% of the sucrose in children's diets. The foods

which contributed the most sucrose to the diets were beverages (37%) and candy (25%). Reports summarizing the food consumption profiles of individuals in different age groups issued by HANES show that sweetened beverages and candy are more frequently consumed by those aged 1 to 17 than any other age group.[12] In the Bogalusa Study, sucrose contributed 18% of the total calories consumed by children.[13]

Sucrose and other sugars are a source of calories but they offer little else nutritionally. Data from the Ten State Survey indicated that there is a high prevalence of dental caries among children in the United States. A recent report, "Evaluation of the Health Aspects of Sucrose as a Food Ingredient," prepared for HEW by the Federation of American Societies for Experimental Biology, concludes that, "Reasonable evidence exists that sucrose is a contributor to the formation of dental caries when used at the levels that are now current and in the manner practiced." The report also states that various factors affect the cariogenicity of sucrose. Among them is the form in which the sucrose is eaten and the frequency of exposure.[14]

The American Society for Clinical Nutrition recently published the proceedings of its symposium titled "Can Disease of Overconsumption be Prevented by Dietary Changes? A critique of the evidence." Participants in the symposium concluded that sucrose, especially when consumed frequently throughout the day, is the dietary component that is most conducive to oral bacterial infection and caries.[15] It has been demonstrated that consumption of snack-type foods between meals has a significant effect on the frequency and severity of dental caries.[16]

The Surgeon General's report, "Healthy People," summarizes a number of studies that have compared the frequency and amount of sugar eaten to dental caries development. Although some show no correlation between dental caries development and the frequency with which sugar is eaten, most demonstrate a positive correlation. In a study of 200 children aged 5 to 13 years Zita *et al.* found a significant positive correlation between the amount of between meal sugar eaten and the prevalence of caries. Weiss and Trithart found that among 783 children 4 and 5 years old there was a positive correlation between the number of meal snacks and dental caries. Fanning *et al.* (45) in 1969, examined 1,266 secondary school children. In those schools where canteens were available where sweets could be purchased, children had a higher incidence of caries than children in schools lacking canteens.[17]

In light of the findings of the studies described, the Department concluded that concern about the quality of children's diets is appropriate. Moreover, these studies demonstrate that there is reason to be concerned about the kind of snacks that children eat. Since snacks contribute a significant proportion of the calories that children consume, it is important that snacks contain nutrients as well as calories if children's diets are to be nutritionally adequate.

III. Development of a Final Rule

A. Method of Analysis

Three broad approaches were considered when the competitive foods rule was developed. One approach would have been to base the rule on the required meal pattern from the school lunch program. This would have meant that any food which satisfied the meal pattern requirement would be approved for competitive sale. Of the substantive comments received on the July 6, 1979 proposal, only twenty people (8%) suggested that the required meal pattern standard be used. The major defect of this approach is that it does not offer a means by which to assess the nutritional contribution of individual foods. Therefore, we concluded that it was not an appropriate standard to use in this rule.

The two other methods of analysis considered in the development of this rule are the food composition approach and the nutrient analysis approach. A considerable number of people commented on each of these. They are discussed in more detail below.

1. *Food Composition.* An analysis of foods under the food composition approach would assess the levels of ingredients such as sugar, fat or salt contained in foods. This approach directly addresses the strong associations between the overconsumption of certain food components and current public health problems. However, as we explain in this section, problems related to the practical application of such an approach preclude its use as the basis for a competitive foods rule at this time.

Many of the comments that the Department received suggested that the rule be designed to limit the amount of sugar, fat, and salt in foods approved for competitive sale in schools. These comments came both from consumers and from members of scientific and professional communities. The concern of consumers about this issue has been well documented. The report "Family Health in an Era of Stress" sponsored by General Mills describes the views on nutrition and diet expressed by approximately 2,000 adults and teenagers who were interviewed. Eighty-four percent termed "fats" a very serious or somewhat serious threat to health, 78 percent said that "sugar or sugar products" posed very serious or somewhat serious threats to health, and 73 percent expressed similar concerns about "salt."[18] In a survey commissioned by Pacific Mutual Life Insurance Company called "Health Maintenance," 570 people with school-aged children were asked how concerned they were about the amount of cholesterol and fats the children have in their daily diets. Seventy-three percent of those people responded that they were very concerned or somewhat concerned.[19]

This concern by consumers is a response to similar expressions of concern by members of the scientific community about the levels of sugar, fat, and salt in the total diet. Despite agreement among many experts about the advisability of reducing consumption of these components in foods, however, the Department encountered three significant practical problems in attempting to fashion a competitive foods rule that would achieve this objective directly. First, although many concerned scientists believe that consumption of sugar, fat, and salt should be reduced, there is not yet clear agreement on the precise levels of these components appropriate in the total diet. Second, and more importantly, even if there were agreement on appropriate levels of these components in the diet as a whole, there is no way to assign an appropriate level of sugar, fat, and salt for each of the individual foods available in the marketplace. Third, even assuming that the first two problems could be resolved, data on the composition of individual foods is inadequate to permit the practical application of a rule which prescribed appropriate levels of all of these components in all foods. These problems are more fully discussed below.

In considering the application of a food composition standard we surveyed recommendations for dietary modification that had been made by various agencies and organizations on the basis of careful review of scientific evidence. We found agreement about general goals but little guidance on what specific standard to adopt. In 1977 the Senate Select Committee on Nutrition and Human Needs recommended that Americans increase their consumption

of complex carbohydrates and "naturally occurring" sugars to approximately 48 percent of energy intake and reduce the consumption of refined and processed sugar to account for approximately 10 percent of total energy intake. The Committee also recommended reduction of overall fat consumption to about 30 percent of an individual's total energy intake, saturated fat to about 10 percent of total energy intake and reduction of cholesterol consumption to about 300 grams per day. Reducing the intake of salt to about 5 grams per day was recommended to limit the intake of sodium.[20] Several international committees on food and coronary heart disease have recommended dietary modification to reduce the amount of fat and sugar that is consumed.[21] The American Heart Association has recommended that the proportion of energy derived from fat not exceed 35% and that recommendation has been supported by the National Academy of Sciences' Food and Nutrition Board.[22]

The Surgeon General's report "Disease Prevention and Health Promotion: Federal Programs and Prospects" recommended actions in nutrition to promote good health but did not suggest specific ideal percentages for food components in the diet. The report states, "Not only is the national diet excessive in terms of total calories, but it also is poorly distributed in sources of calories. Total fat intake, especially animal fats, refined carbohydrates, and salt should be reduced as part of a prudent diet." [23]

The problem of designing a specific food composition standard to apply in a competitive foods rule is made much more difficult by the fact that acceptable levels of fat, sugar, and salt in individual foods necessarily vary. For example, there are individual foods, such as some meats and nuts, which generally are recognized as making positive nutritional contributions to the diet but which have a high proportion of fat. As they have been defined, competitive foods are any foods sold in competition with the federally subsidized meals in schools. They may be available in alternate or a la carte lunch lines, or from vending machines, snack counters, or school stores. This means, essentially, that any food might be termed a competitive food depending on the circumstances of its sale. The difficulty of fashioning a rule which would establish appropriate levels of sugar, fat, and salt for all foods that might be sold in the school thus is considerable.

Although the Department found concern among experts about high levels of sugar, fat, and salt in the diet as a whole, we found that those experts are as yet unable to suggest specific percentage limitations for each individual food available in the marketplace.

The Department asked the nation's leading health officials if, in their opinion, there was a scientific and practical basis for establishing appropriate levels of these components in the full array of individual foods and, if so, what specific standard they would apply. Dr. Arthur C. Upton, the director of the National Cancer Institute, responded by referring to the general dietary recommendations from the Institute's October 1979 "Statement on Diet, Nutrition and Cancer" but he stated that at this time it is not possible to give advice on specific levels of acceptability for fat, sugar, and salt in all foods. [24]

Dr. Mark Hegsted, the Administrator of the Department of Agriculture's Human Nutrition Center, replied that, "A difficulty in establishing appropriate levels [of sugar, fat, and salt], of course, is that we have no standards for appropriate intakes of these whereas we do have the RDA for essential nutrients. Furthermore, while it is possible to establish appropriate levels for the diet as a whole, it will be extremely difficult to find a single appropriate standard to apply to all individual foods." [25]

Dr. Julius B. Richmond, Surgeon General and HEW Assistant Secretary for Health, acknowledged the desirability of preventing excessive dietary intake of fat, salt, and sugar in the diets of Americans but concluded that, "given the limitation of the science base at this stage, we believe that it is not now possible to establish specific levels of acceptability for amounts of these substances in individual foods." [26]

Even if the Department were able to establish a standard for specific acceptable levels of sugar, fat or salt in individual foods, the problem of inadequate food composition data would remain. Information about the amount of fat in many foods is available. Some figures are available for the sodium content of foods, but scientists doubt the validity of these numbers because the techniques used to analyze foods for that nutrient are not reliable. Current knowledge about the total sugar available in individual foods is in general scanty even though sugar content data are available for some types of food. Several government planning and review agencies and some professional organizations have stated that the determination of the nutrient composition of foods is a high research priority in human nutrition.[27] The Department of Agriculture's Human Nutrition Center plans to greatly increase activities related to the generation of food composition data in the 1980's. Until a substantially broader data base is available, however, it will not be possible to apply any food composition standard to the vast array of available foods.

Many commentors asked us to address broad concerns about the composition of the whole diet in a standard which can be used to evaluate individual foods, but they were not able to suggest workable methods for quantitative assessment or to provide the data that are needed for such an assessment. Approximately 54% of the substantive comments that the Department received suggested that the competitive foods rule be designed to limit the amount of sugar, fat, or salt in foods. Forty percent of those comments were from medical, dental or nutrition professionals and organizations, but only four of the fifty-three commentors in that category (8%) offered specific suggestions for appropriate amounts of sugar, fat, or salt in foods. Those four commentors all suggested that percentage values that have been recommended for components in the whole diet be applied to individual foods. None of these commentors discussed how to deal with the problem of individual foods which are generally recognized as making positive contributions to the diet but which contain a high proportion of sugar, fat, or salt. Similarly, the commentors did not address the problem of inadequate food composition data.

Although we have concluded that the substantial practical problems of applying a food composition standard make it an infeasible basis for a competitive foods rule at this time, we share the concern of consumers, professionals, and members of the scientific community about health problems associated with over-consumption of foods high in sugar, fat, or salt. The Department has taken a number of actions to reduce the levels of these components in its child nutrition programs. New regulations for the National School Lunch Program published in August 1979 require schools to serve skim milk, low-fat milk or buttermilk to decrease the fat content of the lunches. These regulations also contain recommendations for menu planning including the recommendation to, "Keep fat, sugar, and salt at a moderate level." In addition, new guidance materials which stress the moderate use of sugar and fat in meal preparation are being developed.

The Department has attempted to reduce sugar and fat levels in commodities purchased and distributed to schools through the Food Distribution Program. For example, we now distribute canned fruit in light syrup rather than fruits packed in heavy syrup. New specifications require that the ground beef purchased for feeding programs contain no more than 22 percent of calories as fat; previously a maximum of 24 percent was specified.

The Department has also made efforts to reduce the amount of sugar in the diets of participants in the Special Supplemental Food Program for Women, Infants and Children (WIC) by proposing to set a maximum level of sugar in WIC cereals. The proposed changes for the food packages provided in the WIC program set a maximum level of 6 grams of sugar per ounce for approved cereals. The Department was able to make specific recommendations about the appropriate level of sugar in cereals because of their unique features. Of primary importance is the fact that manufacturers have made complete food composition information about their products available. Thus, we know the range for the amount of sugar in cereals as well as the amount in each cereal. Also, since much of the sugar in cereal is added during the manufacturing process, it is reasonable to assume that the amount of sugar in the products could be relatively easily reduced.

The Department's concern about the amount of sugar, fat, and salt in the diets of program participants is evidenced by the actions described above which were designed to reduce the consumption of these components. However, we also recognize our responsibility as an administrative agency to promulgate a feasible regulation. In our view, the practical problems discussed in this section make it infeasible to base this regulation on a food composition standard at this time.

2. *Nutrient Analysis.* We concluded that nutrient analysis provides the most effective and feasible basis for a competitive foods rule. Nutrient analysis can be broadly defined as any analysis method which measures levels of nutrients in units of food. The rule specifies a dual method of assessing the nutrient content of individual foods. It calls for both an assessment of the levels of nutrients in units of food as they are commonly served and an assessment of a food's nutrient content in relation to its energy or caloric value. The second measure is called a nutrient density analysis.

The two measures together address the essential objectives which the Department has defined for the competitive foods rule:

1. The rule must identify foods which contribute such low amounts of nutrients as to be considered of "minimal nutritional value."

2. The rule must identify the nutritive contribution of foods in relation to their calorie content.

Foods containing few nutrients as well as foods with calorie contents that are very high in relation to the nutrients that they provide will have lower values in a nutrient density analysis than foods which contain high levels of nutrients or foods with a high proportion of nutrients relative to calories. Foods which contain a large proportion of sugar will have low nutrient density values because sugar provides calories but no other nutrients. Foods which contain a large proportion of fat will also have low nutrient density values because fat provides more than twice as much energy, 9 calories per gram, than the other components of food—protein and carbohydrate—which provide approximately 4 calories per gram. Thus, nutrient density indirectly addresses the concern about sugar and fat.

The principal difficulty in using a nutrient analysis approach is the complexity involved in translating the concept into a workable formula to be applied in a federal competitive foods rule.

B. Application of a Nutrient Analysis Approach in a Competitive Foods Rule

The translation of the nutrient analysis approach into a workable formula to be applied to individual foods raises several important questions including: which nutrients to assess, what units of measurement to use, what standard of reference to use and what value to select as an acceptable level of nutrients. These questions are discussed below.

1. *Nutrients for Analysis.* Roughly 45 vitamins, minerals and other elements which play an essential role in human nutrition have been identified by nutritional scientists. The precise function and necessary levels of many of these nutrients have not yet been identified. The Food and Nutrition Board of the National Academy of Sciences, National Research Council has established Recommended Dietary Allowances (RDA's) for various age groups for the following nutrients: protein, vitamin A, vitamin D, vitamin E, ascorbic acid, folacin, niacin, riboflavin, thiamin, vitamin B_6, vitamin B_{12}, calcium, phosphorus, iodine, iron, magnesium and zinc. To establish the RDA's, the Food and Nutrition Board had to make estimates based on available information. RDA's have been established for these 17 nutrients because scientific data are available to estimate the human requirements for them.

The establishment of RDA's for the other nutrients will be possible only after further research in this area has been conducted. Considerable time and expense will be required to obtain this information.

Food composition information is most widely available for eight of these 17 nutrients: protein, vitamin A, ascorbic acid, niacin, riboflavin, thiamin, calcium and iron. Because deficiencies in these eight nutrients have been associated historically with public health problems, these nutrients have been the ones most commonly studied by researchers. Thus, the technology needed to assess their presence in foods is well established and relatively inexpensive.

Approximately 2% of the substantive commentors questioned the use of only eight specified nutrients as a basis for analyzing the nutrient content of foods. These commentors generally believe that more nutrients should be considered when determining the status of a food under this rule. One comment received from a national soft drink manufacturer stated that the 8 nutrients should be used only as a first test. If a particular product failed this test but the manufacturer could prove that the food contained 5% or more of an additional nutrient, the food would be classified as an approved competitive food under this commentor's proposed approach.

In its rule on nutrition labeling, the Food and Drug Administration (FDA) requires that if a manufacturer chooses to state the nutritional content of a food, the label must contain information about each of the eight commonly analyzed nutrients listed above. In the process of choosing the nutrients that would be required for labeling purposes, FDA asked nutrition professionals to name the most important nutrients. Some suggested that zinc and folacin also be included on the labels, but FDA concluded at the time that the data bases for those nutrients were too limited to permit imposition of such a requirement. They chose the eight specified nutrients because they are the ones that have been associated most commonly with public health problems and because they are the ones about which the most is known.

While current data on the nutritional status of the general population indicate that there may be reason to be concerned about deficiencies of certain micronutrients such as zinc and folacin, few data are available to indicate how much of these nutrients foods contain.

The Department thus cannot analyze the presence of these and other micronutrients in all foods. If nutrients other than the commonly measured eight were incorporated in the standard, we would be unable to treat all foods equally.

As more composition information about micronutrients and more information about the nutritional status of the population becomes available, FDA may expand its labeling requirements to include additional nutrients. The Department would view such action as an indication that sufficient information on these nutrients had become available to justify revision of the competitive foods rule. However, at this time, for the purposes of this rule, we have concluded that analysis of the eight nutrients will enable us to make a meaningful and accurate decision on the nutritional contribution made by different foods. Therefore, the nutrient standard proposed by this rule measures the quantities of protein, vitamin A, ascorbic acid, niacin, riboflavin, thiamin, calcium and iron present in foods.

2. *Units of Measurement.* The Department has determined that individual foods will be evaluated on the basis of two measurements: (1) nutrients in a 100-calorie portion of the food and (2) nutrients in an average portion of the food as it is commonly served.

Both measures can be used to determine the nutrient content of the food, but they serve distinct purposes in the rule. The 100-calorie measure makes possible a relative comparison of all foods. The analysis of nutrients per average serving permits a more realistic assessment of the nutritional contribution of foods as they are commonly consumed. By coupling the 100-calorie measure and the per serving measure, we will be able to evaluate and compare foods on a theoretical, standardized basis and to assess the nutritional contribution of foods as they are commonly consumed by students in school.

Artificially sweetened foods present a special problem. They contain few calories (and few nutrients in the case of those most commonly consumed by children), but may nevertheless satisfy a child's appetite and may thus replace other foods in a child's diet which would provide more nutrients. We therefore propose to analyze artificially sweetened foods on the basis of serving size alone. Because the balance of calories to nutrients has been intentionally altered in these processed foods, the consumption of 100 calories of such products represents unrealistically large quantities. For example, to measure an artificially sweetened soda on a per-100-calorie basis would require an assessment of 3 to 10 gallons of soda depending on how many calories the soda contained. Since it is not meaningful to compare artificially sweetened foods with other foods on a 100-calorie basis, we have concluded that artificially sweetened foods will be analyzed solely on the basis of serving size.

Moreover, since we share the concerns of the scientific community about the health risks resulting from the use of some non-nutritive sweeteners, we are reluctant to adopt a standard that, while restricting the sale of ordinary soft drinks, would permit the sale of soft drinks artifically sweetened with saccharin. The Committee for Study on Saccharin and Food Safety Policy formed by the National Academy of Sciences in response to Congressional mandate [28] summarized the facts which should be considered in the formulation of a policy concerning saccharin. The Committee stated, "Whether as an initiator or promoter, saccharin is a potential carcinogen in humans, but one of currently uncertain consequence and potency in comparison with other carcinogens. In any case, the large number of persons exposed to saccharin justifies serious continued public health concern." The Committee's report further states, "The observation that saccharin use among young children may be increasing suggests that public health officials should take a prudent course of action."

Recently, the National Cancer Institute and the Food and Drug Administration released preliminary findings of an epidemiological study that examined the relationship between the use of artificial sweeteners such as saccharin and cyclamate and the incidence of bladder cancer in humans. Preliminary results indicated no increased risk of bladder cancer among users of artificial sweeteners in the overall study population. However, there was some evidence that the sweeteners may be hazardous. Among three groups of people—those who consumed both diet beverages and sugar substitutes, those who smoked cigarettes heavily and who also made heavy use of artificial sweeteners, and those women who normally would be at low risk for bladder cancer but consumed sugar substitutes or diet beverages—the risk of bladder cancer increased. Heavy use of artificial sweeteners was defined as six or more servings a day of sugar substitute or two or more eight-ounce diet beverages a day. On the basis of this study and previous experiments with laboratory animals, the authors of the study concluded that while saccharin and cyclamate are not strong carcinogens, they should be regarded as potential risk factors for human bladder cancer.[29] In discussing the study results, Dr. Jere Goyan, Commissioner of the Food and Drug Administration, said, "I reiterate my concern about the consumption by so many Americans, especially young people, of large amounts of saccharin. More than half the subjects in this study were 67 years old or older, and therefore consumed much less artificial sweeteners than their children and grandchildren are today. We may have to wait 20 or 30 years to assess the possible effects on our young people of consuming large amounts of a weak carcinogen." [30]

In a letter to the Department of Agriculture, Dr. Arthur Upton, Director of the National Cancer Institute, said, "We share your concern about the use of saccharin by children. Saccharin is of little or no benefit to normal healthy children, and its elimination from their diet involves no risk to them. Hence in the public health sense, it would seem prudent at this time to eliminate foods containing saccharin from school lunches." [31]

Eighty-five of the commentors (3%) expressed concern about the use of saccharin or artificial sweeteners in foods sold in the schools. Of those who commented on the issue, the majority (84%) were concerned citizens.

These comments as well as the recommendations from the scientific community strengthened our view that it is reasonable to make distinctions between naturally and artificially sweetened products, particularly in a regulation that will affect children.

3. *Standard of Reference.* In performing nutrient calculations the Department relied on the USRDA's adapted by the Food and Drug Administration from the Recommended Dietary Allowances (RDA's) which are established by the Food and Nutrition Board, National Academy of Sciences, National Research Council. The USRDA's which are currently in use are based on the RDA's which were established by the Board in 1974.

A handful of commentors were concerned that the Department was not using the most up-to-date values. The Food and Nutrition Board plans to publish new RDA's in 1980. They have made these new RDA values available to professionals prior to publication, but the text that will accompany the values is not yet available. The Food and Drug Administration has as yet made no

changes in the USRDA values. Therefore, we will continue to rely on those established USRDA values for the purposes of this rule.

4. *Level of Nutrients.* Using the nutrient analysis approach as the basis for the proposed rule, it was necessary for the Department to select a minimum level of nutrients for foods acceptable for competitive sale. Sale of foods not containing this minimum level would be restricted during certain hours in schools.

The Department has determined that foods which provide less than 5% of the USRDA for each of the eight specified nutrients per 100 calories *and* per serving will be considered foods of minimal nutritional value. Only the per serving measure will apply to artificially sweetened foods. The sale of foods of minimal nutritional value in schools will be permitted only after the last lunch period of the school day. For example, licorice does not contain even 5% of the USRDA for any one of the eight specified nutrients per 100 calorie quantity or per average serving. Thus, licorice may be sold only after lunch.

In determining that a 5% level would be used for this purpose the Department turned, once again, to the related actions of another federal agency for guidance. The FDA , in its nutrition labeling regulations, allows a manufacturer to claim that a food is a "significant source" of a particular nutrient if that nutrient is present in a serving of food at a level equal to or in excess of 10% of the USRDA for that nutrient. We concluded that if a food which contains 10% of a nutrient may be termed a "significant source" of that nutrient, something less than 10% would be an appropriate test for this rule.

In its labeling rule, the FDA considers less than 2% of the USRDA to be an insignificant quantity of the nutrient in a particular food. The FDA chose the 2% level as the cut off for measurement of nutrients in foods for labeling purposes because scientific techniques for nutrient analysis are not sufficiently sophisticated to provide reliable data about nutrients that are present in foods in very small quantities. FDA has used these 2% and 10% levels in its labeling rule for almost a decade and they are well accepted by professionals and consumers.

The Department concluded, in light of FDA's approach, that a 5% standard was the most reasonable to adopt in the competitive foods rule. While a food which provides 5% of the USRDA for a particular nutrient would not be considered a "significant source" of that nutrient under FDA's rule, it nevertheless makes a positive contribution to the satisfaction of an individual's daily needs for that nutrient.

FDA scientists suggested during a meeting with Department officials that rather than applying a 5% standard to all nutrients, a more desirable approach might be to consider each nutrient individually. Such an approach would relate the required level for each nutrient in foods to the average amount of that nutrient provided by foods in general. This would entail making an inventory of all available foods and determining the amount of each nutrient that each food contains. The approach described is an attractive one because of its greater precision but it would require a great deal of preliminary research which has not yet been done and which cannot feasibly be undertaken for the purposes of this rule.

A few commentors maintained that in proposing the 5% standard, the Department was acting inconsistently with the efforts of FDA which, in its regulation for label statements, requires that percentages of the USRDA be expressed in increments of two percentage points up to and including the 10% level. Although we relied on FDA's characterizations of the nutrient content of individual foods in selecting the 5% level, we did not intend to rely specifically on the use of nutrient labels to administer this rule.

For three primary reasons the use of nutrient labels is not practical for this particular regulatory purpose. First, as we explain in the next section, this rule ultimately identifies categories of foods which cannot be sold competitively until after the last lunch period. Categories are defined primarily for reasons of administrative necessity so that each individual food need not be evaluated. This approach makes it unnecessary for members of the public to use food labels to make determinations about the acceptability of individual foods. The Department will re-evaluate its defined categories as new information becomes available.

The second reason that the Department chooses not to rely on nutrition labeling information in administering this rule is that all foods are not labeled. The FDA requires nutrition labeling only in special circumstances: food product labels must bear nutrition information when any vitamin, mineral or protein is added to the product or when any nutrition claim or information, other than sodium content, appears on a label or in advertising for the food. Many manufacturers label their products voluntarily but it is estimated that in 1978 only approximately 40% of all processed foods were labeled with nutrition information. FDA does not have a record of which specific products are labeled in the entire national food supply.

The range of foods that can be sold competitively is very broad. The Department must make assessments about the nutrient content of foods such as fresh fruits as well as processed products. Since the majority of the foods available in the market do not have nutrition labels, the Department cannot consistently use the labels as tools for assessment. We must rely instead on available food composition information that allows us to make accurate decisions about the nutritional contributions of a wide variety of foods. The most complete food composition information is available in tables of nutritive values which have been derived from chemical analysis of foods. The Department relied on these in making determinations about what foods could be sold competitively.

The third reason for the Department's decision not to use nutrient labels as the practical basis for administering the competitive foods rule is that the figures on the labels are not expressed in a manner consistent with the expressions that appear in food composition tables. As some commentors pointed out, the values between two and ten percent are expressed in even increments on the labels. Each stated value has been rounded. Thus, to judge some foods for the purposes of this rule on the basis of figures from nutrition labels and others on the basis of figures from food composition tables would not be equitable.

The 5% value established to evaluate foods for competitive sale is based on accepted principles reflected in FDA's labeling rule. Because of questions that were raised during the comment period we considered whether it would be more practical to change that 5% value to correspond to the 4% or 6% figures that appear on food labels. We concluded that while nutrition labels provide some useful information, it is not practical to rely on the labels for this regulatory purpose. The Department continues to believe that the established 5% level is an appropriate one for this rule.

5. *Fortification of Foods.* In the proposed competitive foods rule we indicated that we did have some concern about using a nutrient analysis approach because it might encourage manufacturers to fortify foods to meet the nutritional requirements of the rule. The Department received many comments related to this issue; 243 of the 3,067 commentors (8%) expressed

concern about the influence that this rule might have on fortification practices. Most people who commented discussed the danger that this rule could, at least in theory, encourage inappropriate fortification practices.

Public concern about fortification has been expressed in other contexts. In December, 1979 proposed regulations on food labeling practices were issued jointly by HEW, USDA, and FTC after a series of public meetings had been held and public comments had been solicited. Food fortification was one of the issues which stimulated many comments. Of the 1,103 commentors who discussed the advisability of fortifying foods, 84% approved of the practice, but many of these commentors had some reservations about it. These are reflected in the proposal which states, "Public reservations thus stem largely from concern about overfortification and the potential for inappropriate fortification." [32]

Historically, the fortification of foods has occurred in response to a nutriitional need in a clearly defined population. Specified nutrients are added to foods in an attempt to correct deficiencies that have been identified. With advances in food technology and increases in the number of formulated products on the market, nutrients have been added to an increasing number of foods. This trend has raised questions about the appropriateness of some fortification practices. Professionals are concerned that indiscriminate fortification of foods may mislead the public.

Traditionally nutritionists have promoted a diet composed of a wide variety of conventional foods because knowledge of human nutrient requirements is incomplete. Experience has shown, as new essential nutrients are discovered, that conventional foods supply the nutrients that are known to be essential as well as those micronutrients and food components which we need but which have not yet been identified. Some fortified foods may be inferior to those that they replace in the diet. For example, a manufacturer may add vitamin C, a recognized essential nutrient, to a product. A person who consumes that product can benefit from the specific added nutrient but may be deprived of some other food components such as fiber or some micronutrients that are contained in the conventional food but not in the replacement product.

A related concern is that the overfortification of foods could cause an imbalance of nutrients or the excessive intake of some nutrients in the diet. It is relatively inexpensive to add certain nutrients to foods but these are not necessarily the ones that are lacking in most peoples' diets. People who rely on fortified foods to supply nutrients may believe that they are eating well but may actually have inadequate diets.

There is also some apprehension because of the possibility that people who rely on fortified products may be unable to distinguish those foods from their unfortified counterparts. A person who is accustomed to drinking a fortified beverage, for example, may assume that all beverages of that same flavor or type are equally nutritious and may consume a product that seems to be the same but actually provides little nutritionally.

The nature of the foods that are fortified is another issue of concern. Nutrients can be added to any food but many nutritionists believe that there are some foods which should not be fortified. They maintain that the addition of nutrients to foods which contain large amounts of sugar or fat, for example, may be counterproductive because that practice will encourage people to eat those foods. As we have pointed out earlier in this preamble, concern already exists about the overconsumption of sugar and fat because of the documented associations between those food components and public health problems.

Many of the general concerns discussed above are specifically raised by the competitive foods rule. For example, it may be particularly difficult for children to distinguish between fortified foods and their nonfortified counterparts. The Department believes that it is important to provide examples of good nutritional practices which can be easily understood by children in the schools. Because of each of the reasons discussed, we would oppose the fortification of any foods which are identified in this rule as foods of minimal nutritional value.

The foods which this rule restricts for sale in competition with federally subsidized meals in the schools are those which contain few, if any, nutrients per 100 calorie measure and per serving of the food. They are foods which are generally eaten as snacks rather than as components of meals. They are also foods which generally are not fortified. The addition of nutrients to any of the foods identified in this rule as foods of minimal nutritional value could qualify them for competitive sale. However, the Department believes that fortification of foods simply to satisfy the technical requirements of this rule rather than in response to identified public health problems would be inappropriate.

The subject of inappropriate fortification practices has been widely addressed. Most recently the Food and Drug Administration has published "General Principles for the Addition of Nutrients to Foods," a policy statement intended to promote the rational addition of nutrients to foods. The document discusses the types of foods that are appropriate to fortify: "Although, as a theoretical matter, most types of food can be fortified under the general principles expressed in this document, FDA emphasizes that, as a matter of policy, it does not consider it appropriate or reasonable to fortify certain classes of food such as fresh produce, fresh meat, poultry or fish products, sugars, or snack foods such as candies and carbonated beverages. * * * FDA sees no reason to add nutrients to fresh produce, meat, poultry, or fish products. The use of these foods is firmly established by customary dietary practice, and their role in a balanced diet is well understood by the public. FDA also believes it is inappropriate to fortify snack foods such as candies and carbonated beverages. These foods are not considered by the public as components of meals, and even if snack foods are used with meals, their nutritional contribution is, and is understood by the public to be incidental. To date, neither the public nor the scientific community has considered snack foods to be appropriate carriers for added nutrients, given the general adequacy and diversity of the national food supply. Their fortification could readily mislead consumers to believe that substitution with fortified snack foods would insure a nutritionally sound diet. Moreover, such fortification would disrupt public understanding about the nutritional value of individual foods and thereby promote confusion among consumers and make it more difficult for them to construct diets that are nutritionally neither excessive or deficient." [33]

The Food and Nutrition Board of the National Academy of Sciences has also addressed the issue of inappropriate fortification. The Board published a statement, "General Policies in regard to Improvement of Nutritive Quality of Foods," [34] which lists conditions under which fortification is appropriate. In a report entitled "Technology of Fortification of Foods," the Food and Nutrition Board's Committee on Food Protection relies on these general policies in making a determination about soft drinks: "These (soft drinks) are products defined by the existing standard of identity for carbonated soda water. We believe that such products

should be treated as a pure refreshment and should not be the subject of fortification. . . . For this reason, on which our views concur with those expressed earlier by the Food and Nutrition Board of the National Academy of Sciences, we have not worked on the addition of nutrients to soda water.[35]

The joint expert committee on nutrition of the World Health Organization and the Food and Agriculture Organization of the United Nations has also addressed the issue of the fortification of soft drinks in the report, "Food Fortification, Protein—Calorie Malnutrition." In a discussion of the selection of foods to which nutrients might be added the report says, "special mention should be made of sugar soft drinks, and alcohol beverages as potential vehicles * * *. Special problems are raised when foods whose excessive consumption is discouraged by nutritionists are selected as potential vehicles for fortification. Fortification of these products with properly selected nutrients could increase their nutritive value and thus reduce to some extent the disadvantage of their consumption in large quantities. It must be borne in mind, however, that there is a danger that such fortification might frustrate the endeavors that are being made, or might be made, to check excessive consumption of these products and might even be used as publicity in their favor * * *. The Committee considered that, as a general rule, it is preferable not to include such products among the possible vehicles for fortification programs." [36]

Many commentors suggested that the competitive foods rule distinguish between fortified foods and those that do not contain added nutrients. We consulted the FDA to determine the feasibility of such an approach. While FDA does require that foods to which vitamins, minerals, or protein have been added bear nutrition labels, a list of these products is not maintained. It would thus be impossible to identify all of the products on the market to which nutrients have been added without examining all of the specific product labels. In addition, although it would be possible to determine from each label that nutrients have been added to the food, it would not be possible to determine what proportion of a particular nutrient in a product was naturally occurring and what proportion had been added artificially. Thus a distinction in the competitive foods rule between fortified and unfortified products would be difficult to administer at this time.

The department endorses the guidelines for fortification that have been established by FDA and the fortification policies developed by committees on nutrition. We have stated that the intention of this rule is not to encourage the fortification of foods. Commentors have strongly supported this policy as they express concern about the potential for inappropriate fortification. We expect that industry will continue to add nutrients to foods in response to identified public health problems and that new fortification practices will not be instituted specifically in response to this rule. It is worth noting that roughly less than 0.5% of the dollar value of candy and less than 0.6% of the dollar value of soda sold in the U.S. would be affected by this rule. The rule restricts the sale of foods which generally are not fortified today and, as is evident from the statements above, should not be fortified. If inappropriate fortification of foods identified in this rule as food of minimal nutritional value occurs, the Department will immediately take appropriate action to restrict such practices with respect to competitive foods.

C. Identification of Foods of Minimal Nutritional Value

After establishing a specific standard to define foods of minimal nutritional value, the Department attempted to identify those foods that fell below the standard and therefore could be sold only after the last lunch period. The 5% standard was applied to a wide array of individual foods using nutrient values from food composition data that were available to the Department.

We contracted with three universities—Colorado State, Utah State, and Case Western Reserve—to supply information relating to the nutrient composition of several thousand individual foods. Subsequently, we asked Case Western Reserve University to do some additional calculations with respect to the approximately 2,300 food items and recipes it had already analyzed. The University calculated the percentage of the USRDA for each of seventeen specified nutrients provided by a 100-calorie quantity and by an individual serving of each food. This information allowed us to compare each food to the standard stated in the proposed rule.

During this process, it became clear that it is necessary and reasonable to identify foods by category. The Department recognizes that there are important similarities among the individual items initially identified as foods of minimal nutritional value by application of the 5% standard: these foods contain similar ingredients.

In addition, the Department was aware of numerous practical and policy reasons for adopting a categorical approach. First, the nutritional data available were not sufficiently detailed to permit analysis of all of the individual food items that are on the market. In particular, almost no information was available for items by brand name.

Second, the development of a list of approved individual food items for competitive sale would impose a monumental administrative burden at the federal level. Since there are many thousands of food items sold in grocery stores and thousands more introduced into the market each year, the Department would have to spend considerable effort reviewing these individual items to determine whether they did or did not meet the competitive food standard. Under this system, we would have to obtain specific composition information on each product from the manufacturer and review each food every time a formula adjustment was made by the manufacturer.

Moreover, implementation of a federal rule that identified thousands of individual foods for competitive sale would result in an immense administrative burden at the local level as well. The implementation of federal regulations pertaining to the National School Lunch Program takes place in 92,000 participating schools. Under a competitive foods rule, each of these schools will need to know which foods can and cannot be sold competitively in the school. It would not be practical to expect each school to maintain a current list of all individual foods identified by the Department as foods of minimal nutritional value since such a list would be lengthy and would be constantly changing due to the introduction of new items and reformulation of existing items in the market place.

In its comments on the April 25 proposal, Hershey Foods suggested that one way to avoid these problems of USDA developing and maintaining a list of individual foods would be for manufacturers to certify directly to school officials that their products met objective nutritional criteria established by the Department. Alternatively, Hershey suggested that a list of foods approved for competitive sale could be compiled by USDA on the basis of certification or other information submitted to the Department by the manufacturers. Hershey commented that the Department could authorize a USDA seal to be placed on the labels of approved products for ease of

identification by school officials. We rejected these approaches in order to avoid even the appearance of Department endorsement of specific products.

Based on our review of the nutrient content of individual foods, it became clear that all or virtually all foods in certain categories provide less than 5% of the USRDA for each of the eight specified nutrients per 100 calories and per serving. We have therefore defined four categories of foods of minimal nutritional value: soda water, water ices, chewing gum, and certain candies. These candies are subcategorized to include hard candies, jellies and gums, marshmallow candies, fondants, licorice, spun candies, and candy coated popcorn. In describing these categories, the Department relied on descriptions used by industry, classifications used in nationwide surveys, and Standards of Identity established by the Food and Drug Administration in the Code of Federal Regulations. For the purpose of this rule the Department has determined serving sizes for each of the categories. They are:

Soda—12 fluid ounces
Water Ices—3 fluid ounces
Candies—1.5 ounces
Gum—1 stick or piece

These units correspond with the units in which these products are frequently sold or consumed.

The Department recognizes that a regulatory scheme based entirely on a categorical approach cannot be precise. To insure greater precision in the application of the rule, a procedure is provided for consideration of individual foods and additional categories of foods. The petition procedure as set forth below differs from the one described in the July 6 proposal. Changes were made in light of the comments to provide a more workable procedure. Specifically, although persons may petition the Department to remove individual foods from the established categories of foods of minimal nutritional value, additional foods will not be restricted for competitive sale on an individual basis. Rather, the Department will review petitions requesting that new *categories* of foods of minimal nutritional value be designated. Because of the large number of individual foods available in the marketplace and the constant development of new food products, the Department believes that it would not be feasible to maintain a list of individual foods which failed the nutrient test established in the rule and thus were restricted for competitive sale.

The procedure will operate as follows. A person may petition the Department to approve for competitive sale an individual food which falls into a category of foods of minimal nutritional value restricted from sale in schools until after the last lunch period by submitting a nutrient analysis of the food demonstrating that it provides 5% or more of the USRDA for any of the eight specified nutrients per 100 calories or 5% or more of the USRDA for any of the eight specified nutrients per serving. (In the case of artificially sweetened foods, only the per serving measure will apply.) Upon such a showing, the Department will inform the petitioner that the food is an approved competitive food.

A person may petition the Department to add a new *category* to the list of previously identified categories of foods of minimal nutritional value. Any such new category must be composed primarily of foods which provide less than 5% of the USRDA for each of the eight specified nutrients per 100 calories and less than 5% of the USRDA for each of the eight specified nutrients per serving. (In the case of artificially sweetened foods, only the per serving measure will apply.) Along with the request, the petitioner must identify and define the category by providing a general description and by submitting a list of the ingredients which these foods usually contain. It is important that the petitioner keep in mind that the food category must be easily identified and understood by local school districts.

If the Department determines from a review of the ingredients that the proposed new category should be classified as a category of foods of minimal nutritional value, the Department will publish a notice of proposed rulemaking indicating its intention to so classify it, stating the reasons for this action, and soliciting public comments. The public comment procedure will be used to solicit information from manufacturers and other interested members of the public about the description and the composition of the foods in the proposed category. The Department may in addition conduct its own food composition analysis of those foods. On the basis of the information available to it, the Department will determine whether the proposed category should be classified as a category of foods of minimal nutritional value.

By May 1 and November 1 of each year, the Department will amend Appendix B of Parts 210 and 220 to reflect the results of any new Departmental decisions on such petitions, provided that there is a need to add a category of foods of minimal nutritional value, or a need to delete an individual food from a previously identified category of foods of minimal nutritional value.

The Department recognizes, from our own review of the available food composition data and from information submitted during the comment period, that there are some individual products which can be defined by the 5% standard as "foods of minimal nutritional value" but which are not part of groups of foods which can be easily categorized. For example, data show that some cakes contain less than 5% of the USRDA for each of the eight specified nutrients per 100 calories and per serving. But many cakes do provide substantially more nutrients. Because there are so many kinds of cakes it is not possible to define a category of products to be restricted nor is it possible to accurately describe specific cakes. There are, for example, many recipes for "chocolate cake," all with different ingredients or proportions of ingredients. Many would satisfy the nutrient test of the rule but some may not. Distinguishing among them would be an impossible administrative task requiring analysis of a wide array of recipes from thousands of local schools. These practical contraints dictate that some individual foods which fail the 5% nutrient test established by the rule will nonetheless remain available for competitive sale throughout the school day.

IV. Implementation Issues

A. Local Rules

This rule identifies foods that clearly make the least nutritional contribution to a child's diet. The test used to define foods of minimal nutritional value is a conservative one. Like the Department's meal pattern requirements for the school lunch program, it represents a baseline, minimum standards approach. This rule should in no way be construed as endorsing all other foods.

While no School Food Authority may adopt a less comprehensive competitive foods policy, any State or locality may develop more comprehensive rules. Thus, those States and localities which have already adopted rules that are more comprehensive than this proposal are urged to continue those rules. This is consistent with the general proposition that States may develop any regulation concerning the National School Lunch Program and School Breakfast Program as long as the local regulation does not conflict with federal regulations (7 CFR 210.19). Recognizing that existing

regulations for the school food programs establish *minimum* standards for the receipt of federal funds, many school districts have adopted more rigorous standards in order to provide superior meals to students. School districts may wish to continue this leadership in the competitive foods area.

In adopting a conservative, baseline approach to the regulation of competitive foods, the Department recognizes that there is presently considerable interest in this issue at the local level. The public comments on the Department's April 25, 1978, December 15, 1979, and July 6, 1979 notices concerning competitive foods from parents of school age children reflected parents' desire and willingness to participate in the development of local competitive foods policies.

Testimony at the public hearings indicated that, in the past, competitive foods decisions at the local level were frequently made without the knowledge or participation of parents. In communities where there is no competitive foods policy, many parents at the public hearings stated that they were willing to participate in establishing one. A recent Gallup Poll revealed that 67 percent of parents of children attending schools that offer the school lunch program believed that candy should not be available for sale in schools while 65 percent believed chewing gum should not be available. Thus, it is apparent that parents have definite ideas about competitive foods policy and considerable interest in participating in its formulation.

The Department encourages parents, students, school officials, teachers, school food service personnel, and nutrition experts to work together to design local policies. We believe it is desirable for local communities to consider local needs in the development of a competitive foods policy which uses the federal rule as a minimum standard. The school nutrition programs are a partnership of local, State and federal agencies. Local and State officials have the authority to implement a more comprehensive rule—one that may go beyond the Department's minimal rule. Similarly, the Department may, in its continuing review of this issue determine that in the future a more comprehensive federal rule is desirable.

B. Age Distinctions

The Department received a few comments on the July 1979 proposal that favored age distinctions in the rule that would allow older children access to foods of minimal nutritional value not available to younger children. The majority of these comments came from students.

The legislative history of the competitive foods amendment does not discuss such a distinction. Of those States and localities which have competitive foods policies, only a handful make age distinctions. Many commentors on both the April 1978 and July 1979 proposals opposed making age distinctions in the rule on the ground that because nutrition education programs are still new in most areas, children of all ages lack the information necessary to make informed food choices. These commentors indicated that until such time as all children have adequate nutrition education programs, any rule should apply equally to children of all ages. The Department is taking steps to provide nutrition education training to children to alleviate this lack of knowledge with the Nutrition Education and Training (NET) program. The NET program is a result of Pub. L. 95–166 (enacted in November 1977), the same law that initiated the competitive foods rule. These programs are just getting underway. Progress should be noted in schools during the next few years.

The Department believes that since its standard defines as foods of minimal nutritional value those foods which have the least to offer nutritionally, the rule should apply to all age groups. Where local communities develop more comprehensive, competitive foods policies, they may wish to consider whether age distinctions may be appropriate in their additional regulations.

C. Time and Place

This rule would prohibit the sale to children of foods of minimal nutritional value throughout the school until after the end of the last lunch period of the school day. In restoring the Secretary's authority to regulate the sale of competitive foods, Congress sought to protect the nutritional integrity of the federal school nutrition programs and to foster a school environment in which nutrition education and food service policies reinforce each other in promoting good eating habits among students. We believe that a rule permitting the sale to children of foods of minimal nutritional value before lunch or in areas of the school outside the cafeteria could not accomplish these central objectives of the 1977 competitive foods amendment.

If immediately outside the cafeteria—or anywhere else in the school—foods of minimal nutritional value could be sold in vending machines or at snack counters, it is doubtful whether the sale of these foods would be curtailed. Similarly, if students were permitted to purchase such foods in the morning hours it is unlikely that their consumption in place of the more nutritious foods in the federal school nutrition programs would be reduced. Many of the commentors agreed with the position taken in the proposed rule on this issue. Although 25 commentors felt the restriction should apply during meal periods only, or a half hour before to a half hour after the meal periods, 851 commentors felt that the restriction was reasonable and necessary if this rule is to be effective. An additional 206 commentors stated that the restriction should be for the entire school day throughout the school premises.

Our decision to retain unchanged the provision of the proposed rule with respect to time and place of application reflects our conclusion that such scope is essential if the rule is to carry out the fundamental purposes of the statute.

D. Implementation Date

This final rule must be implemented no later than July 1, 1980. The Department encourages schools to work towards the July 1 implementation date of this final rule by phasing out the foods of minimal nutritional value at this time. Schools may elect to implement the rule immediately and we urge them to do so as soon as is feasible prior to the July 1 deadline.

Four of the technical commentors strongly urged that this rule be implemented at the beginning of the school year and not in the middle of a school year. Three of these commentors were State staff who were well aware of the difficulties schools would have if the rule were implemented in the middle of a school year. These commentors stated that schools would have a difficult time breaking or negotiating contracts with vendors and that there would be insufficient time to publicize the requirements of the rule, as well as other local burdens. The Department is aware of these problems and is responding by requiring implementation of the final rule at the beginning of the school year.

V. Labeling and Advertising

In making this rule final, the Department is aware of the possibility that manufacturers may adopt labeling practices or make advertising claims concerning competitive foods which may mislead the public. We emphasize that this rule does not and is not intended to designate any food as nutritious. The rule simply restricts the sale in schools during part of the school day of some foods which make a

minimal nutritional contribution to the diet.

The Department has carefully avoided the designation of foods as nutritious or non-nutritious, by the terms of this rule, and expects similar restraint on the part of manufacturers in promotion of their products. Any labeling or advertising claims concerning a food's status under this competitive foods rule will be carefully scrutinized for accuracy. We would view as inaccurate and misleading, for example, an advertisement that a particular product had been approved by USDA. The Federal Trade Commission has been advised of our concerns about this issue.

Footnotes

1. In order to qualify for federal reimbursement, a "Type A" school lunch must contain specified portions from four food groups. Other foods may be served along with these Type A foods.

2. Report of the Task Force on the Evidence Relating Six Dietary Factors to the Nation's Health, sponsored by the American Society for Clinical Nutrition, in the American Journal of Clinical Nutrition, Supplement Volume 32, No. 12, December 1979.

3. U.S. Department of Health, Education, and Welfare, "Disease Prevention and Health Promotion: Federal Programs and Prospects" Report of the Departmental Task Force on Prevention, and "Health People" Background Papers, A Report to the Surgeon General by The Institute of Medicine, National Academy of Sciences, 1979.

4. National Cancer Institute, "Statement on Diet, Nutrition and Cancer" before the Senate Committee on Agriculture, Nutrition and Forestry, Subcommittee on Nutrition, October 2, 1979.

5. Ten-State Nutrition Survey, 1968–1970, Center for Disease Control, Atlanta, Georgia. *DHEW Publication No. (HSM) 72–8134, 1970.*

6. The Health and Nutrition Examination Survey (HANES), United States, 1971–72, Dietary Intake and Biochemical Findings, National Center for Health Statistics. *DHEW Publication No. 74–1219–1, 1974.*

7. Frank, Gail C. et al. Dietary Studies and the Relationship of Diet to Cardiovascular Disease Risk Factor Variables in Ten Year Old Children. The Bogalusa Heart Study. *The American Journal of Clinical Nutrition.* Volume 31. February 1978.

8. *Ibid.*

9. HANES, *supra* note 3.

10. Hanes, *supra* note 3; Nutrition Surveillance, Center for Disease Control, *DHEW Publication No. (CDC) 77–8295,* December, 1975.

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12. Dresser, Connie M., Eating Styles Today: Implications of the HANES Food Consumption Survey, National Center for Health Statistics, presented at the American Dietetic Association 61st Annual Meeting, 1978.

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19. Louis Harris and Associates, Inc., "Health Maintenance," commissioned by Pacific Mutual Life Insurance Co., November, 1978.

20. United States Senate, Select Committee on Nutrition and Human Needs, "Dietary Goals for the United States, second edition," December, 1977.

21. "Round Table on Comparison of Dietary Recommendations in Different European Countries," European Nutrition Conference, Munich, Germany, 1976, Metabolism 21:210–214, 1977.

22. National Academy of Sciences, National Research Council, Food and Nutrition Board, "Recommended Dietary Allowances," eighth revised edition, 1974.

23. U.S. Department of Health, Education and Welfare, "Disease Prevention and Health Promotion: Federal Programs and Prospects" Report of the Departmental Task Force on Prevention, and "Healthy People" Background Papers, A Report to the Surgeon General by the Institute of Medicine, National Academy of Sciences, 1979.

24. Communication from Arthur C. Upton, M.D., Director, National Cancer Institute, Bethesda, Maryland, December 27, 1979.

25. Communication from Dr. D. Mark Hegsted, Administrator, Human Nutrition Center, USDA, Washington, D.C., January 18, 1980.

26. Communications from Julius B. Richmond, M.D., Assistant Secretary for Health and Surgeon General, Department of Health, Education and Welfare, Washington, D.C., January 11, 1980.

27. U.S. Department of Agriculture, "Food and Nutrition for the 1980's: Moving Ahead," Washington, D.C., April, 1979.

28. Assembly of Life Science/National Research Council and the Institute of Medicine, National Academy of Sciences, Committee for a Study on Saccharin and Food Safety Policy.

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29. Progress Report to the Food and Drug Administration from the National Cancer Institute, concerning the National Bladder Cancer Study, The National Cancer Institute, Bethesda, Maryland.

30. Press Release, U.S. Department of Health, Education and Welfare, The National Cancer Institute, Bethesda, Maryland, December 21, 1979.

31. Communication from Arthur C. Upton, M.D., Director, National Cancer Institute, Bethesda, Maryland, December 27, 1979.

32. **Federal Register,** Food Labeling, tentative positions of agencies, December 21, 1979.

33. FDA Fortification Guidelines, January 25, 1980.

34. Food and Nutrition Board, National Research Council, General policies in regard to improvement of nutritive quality of foods. Policy statement. National Academy of Sciences, Washington, D.C., 1973.

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Accordingly, Part 210 is amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

1. § 210.2 is amended by redesignating (h–1) thru (h–7) as (h–2) thru (h–8) and adding new paragraphs (c–3), (c–4) and (h–1) to read as follows:

§ 210.2 Definitions.

* * * * *

(c–3) "Competitive foods" means any foods sold in competition with the National School Lunch Program. This includes any food that is sold as a separate item even if it is also a component of the school lunch.

(c–4) "Competitive foods approved by the Secretary" means all foods sold in competition with the National School Lunch Program to children on school premises from the beginning of the school day until after the last lunch period with the exception of categories of foods of minimal nutritional value as listed in Appendix B of this part.

* * * * *

(h–1) "Foods of minimal nutritional value" means (1) in the case of artificially sweetened foods, a food which provides less than 5 percent of the USRDA for each of eight specified nutrients per serving; (2) in the case of all other foods, a food which provides less than 5 percent of the USRDA for each of eight specified nutrients per 100 calories *and* less than 5 percent of the USRDA for each of eight specified nutrients per serving. The eight nutrients to be assessed for this purpose are: protein, vitamin A, vitamin C, niacin, riboflavin, thiamin, calcium, and iron. Categories of foods of minimal

nutritional value are listed in Appendix B of this part.

2. § 210.15b is revised to read as follows:

§ 210.15b Competitive food services.

(a) State agencies and School Food Authorities shall establish such rules or regulations as are necessary to control the sale of foods in competition with a school's nonprofit food service under the program, *Provided,* That such regulations shall not authorize the sale of foods in the categories of foods of minimal nutritional value as listed in Appendix B of this part on the school premises from the beginning of the school day to the end of the last lunch period. The sale of competitive foods approved by the Secretary may be allowed at the discretion of the State agency and School Food Authority provided that the proceeds from the sale of such foods inure to the benefit of the school's nonprofit meal program or to the school or to student organizations approved by the school.

(b)(1) Any person may submit a petition to FNS requesting that an individual food be exempted from a category of foods of minimal nutritional value listed in Appendix B. In the case of artificially sweetened foods, the petition must include a statement of the percent of USRDA for the eight nutrients listed in § 210.2(h–1) that the food provides per serving and the petitioner's source of this information. In the case of all other foods, the petition must include a statement of the percent of USRDA for the eight nutrients listed in § 210.2(h–1) that the food provides per serving and per 100 calories and the petitioner's source of this information. The Department will determine whether or not the individual food is a food of minimal nutritional value as defined in § 210.2(h–1), and will inform the petitioner in writing of such determination, and the public by notice in the **Federal Register** as indicated under section (b)(3).

(b)(2) Any person may submit a petition to FNS requesting that foods in a particular category of foods be classified as foods of minimal nutritional value as defined in § 210.2(h–1). The petition must identify and define the food category in easily understood language, list examples of the foods contained in the category and include a list of ingredients which the foods in that category usually contain. If, upon review of the petition, the Department determines that the foods in that category should not be classified as foods of minimal nutritional value, the petitioner will be so notified in writing. If, upon review of the petition, the Department determines that there is a substantial likelihood that the foods in that category should be classified as foods of minimal nutritional value as defined in § 210.2(h–1), the Department shall at that time inform the petitioner. In addition, the Department shall publish a proposed rule restricting the sale of the foods in that category, setting forth the reasons for this action, and soliciting public comments. On the basis of comments received within 60 days of publication of the proposed rule and other available information, the Department will determine whether the nutrient composition of the foods indicates that the category should be classified as a category of foods of minimal nutritional value. The petitioner shall be notified in writing and the public shall be notified of the Department's final determination upon publication in the **Federal Register** as indicated under section (b)(3).

(b)(3) By May 1 and November 1 of each year, the Department will amend Appendix B to exclude those individual foods identified under section (b)(1), and to include those categories of foods identified under section (b)(2), *Provided,* That there are necessary changes.

PART 220—SCHOOL BREAKFAST PROGRAM

Accordingly, Part 220 is amended as follows:

1. § 220.2 is amended by adding new paragraphs (c–1), (c–2) (i–1) to read as follows:

§220.2 Definitions.

* * * * *

(c–1) "Competitive foods" means any foods sold in competition with the School Breakfast Program. This includes any food that is sold as a separate item even if it is also a component of the breakfast meal.

(c–2) "Competitive foods approved by the Secretary" means all foods sold in competition with the School Breakfast Program to children on school premises from the beginning of the school day until after the last lunch period with the exception of categories of foods of minimal nutritional value as listed in Appendix B of this part.

* * * * *

(i–1) "Foods of minimal nutritional value" means (1) in the case of artificially sweetened foods, a food which provides less than 5 percent of the USRDA for each of eight specified nutrients per serving; (2) in the case of all other foods, a food which provides less than 5% of the USRDA for each of eight specified nutrients per 100 calories *and* less than 5% of the USRDA for each of eight specified nutrients per serving. The eight nutrients to be assessed for this purpose are: protein, vitamin A, vitamin C, niacin, riboflavin, thiamin, calcium and iron. Categories of foods of minimal nutritional value are listed in Appendix B of this part.

2. § 220.12 is revised to read as follows:

§ 220.12 Competitive food services.

(a) State agencies and School Food Authorities shall establish such rules or regulations as are necessary to control the sale of foods in competition with a school's nonprofit food service under the Program, *Provided,* That such regulations shall not authorize the sale of foods in the categories of foods of minimal nutritional value as listed in Appendix B of this part on the school premises from the beginning of the school day to the end of the last lunch period. The sale of competitive foods approved by the Secretary may be allowed at the discretion of the State agency and School Food Authority provided that the proceeds from the sale of such foods inure to the benefit of the school's nonprofit meal program or to the school or to student organizations approved by the school.

(b)(1) Any person may submit a petition to FNS requesting that an individual food be exempted from a category of foods of minimal nutritional value listed in Appendix B. In the case of artificially sweetened foods, the petition must include a statement of the percent of USRDA for the eight nutrients listed in § 220.2(i–1) that the food provides per serving and the petitioner's source of this information. In the case of all other foods, the petition must include a statement of the percent of USRDA for the eight nutrients listed in § 220.2(i–1) that the food provides per serving and per 100 calories and the petitioner's source of this information. The Department will determine whether or not the individual food is a food of minimal nutritional value as defined § 220.2(i–1), and will inform the petitioner in writing of such determination, and the public by notice in the **Federal Register** as indicated under section (b)(3).

(b)(2) Any person may submit a petition to FNS requesting that foods in a particular category of foods be classified as foods of minimal nutritional value as defined in § 220.2(i–1). The petition must identify and define the food category in easily understood language, list examples of the foods contained in the category and include a list which the foods in that category usually contain. If, upon review of the petition, the Department determines that

the foods in that category should not be classified as foods of minimal nutritional value, the petitioner will be so notified in writing. If upon review of the petition, the Department determines that there is a substantial likelihood that the foods in that category should be classified as foods of minimal nutritional value as defined in § 220.2(i–1), the Department shall at that time inform the petitioner. In addition, the Department shall publish a proposed rule restricting the sale of the foods in that category, setting forth the reasons for this action, and soliciting public comments. On the basis of comments received within 60 days of publication of the proposed rule and other available information, the Department will determine whether the nutrient composition of the foods indicates that the category should be classified as a category of foods of minimal nutritional value.

The petitioner shall be notified in writing and the public shall be notified of the Department's final determination upon publication in the **Federal Register** as indicated under section (b)(3).

(b)(3) By May 1 and November 1 of each year, the Department shall amend Appendix B to exclude those individual foods identified under section (b)(1), and to include those categories of foods identified under section (b)(2), *Provided* That there are necessary changes.

Appendix B—Categories of Foods of Minimal Nutritional Value

(1) Soda Water—As defined by 21 CFR 165.175 Food and Drug Administration Regulations except that artificial sweeteners are an ingredient that is included in this definition.

(2) Water Ices—As defined by 21 CFR 135.160 Food and Drug Administration Regulations except that water ices which contain fruit or fruit juices are not included in this definition.

(3) Chewing Gum—Flavored products from natural or synthetic gums and other ingredients which form an insoluble mass for chewing.

(4) Certain Candies—Processed foods made predominantly from sweeteners or artificial sweeteners with a variety of minor ingredients which characterize the following types: (a) Hard Candy—A product made predominantly from sugar (sucrose) and corn syrup which may be flavored and colored, is characterized by a hard, brittle texture, and includes such items as sour balls, fruit balls, candy sticks, lollipops, starlight mints, after dinner mints, sugar wafers, rock candy, cinnamon candies, breath mints, jaw breakers and cough drops.

(b) Jellies and Gums—A mixture of carbohydrates which are combined to form a stable gelatinous system of jelly-like character, and are generally flavored and colored, and include gum drops, jelly beans, jellied and fruit-flavored slices.

(c) Marshmallow Candies—An aerated confection composed of sugar, corn syrup, invert sugar, 20% water and gelatin or egg white to which flavors and colors may be added.

(d) Fondant—A product consisting of microscopic-sized sugar crystals which are separated by a thin film of sugar and/or invert sugar in solution such as candy corn, soft mints.

(e) Licorice—A product made predominantly from sugar and corn syrup which is flavored with an extract made from the licorice root.

(f) Spun Candy—A product that is made from sugar that has been boiled at high temperature and spun at a high speed in a special machine.

(g) Candy Coated Popcorn—Popcorn which is coated with a mixture made predominantly from sugar and corn syrup.

(Sec. 17, Pub. L. 95–166, 91 Stat. 1345 (42 U.S.C. 1779)).

Note.—In accordance with Executive Order 12044 a copy of the detailed final impact analysis statement for this final regulation is available at the Office of the Director, School Programs Division, USDA–FNS, Washington, D.C. 20250 during regular business hours (8:30 a.m. to 5:00 p.m., Monday through Friday).

Dated: January 25, 1980.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

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