

§ 911.23 Recapture of payments.

If within ten years after the acquisition of the facility, under this part, either the owner of the facility ceases to be a public or nonprofit private agency or organization, or the facility ceases to be used for the purpose for which it was acquired, the Department shall be entitled to recover from the agency or other owner of the facility an amount, which bears to the then value of the facility, or so much thereof as constituted an approved project award or awards, the same ratio as the amount of such Federal funds bore to the cost of the facility financed with the aid of such funds. Such value shall be determined by agreement of the parties or by action brought in the United States District Court for the district in which such facility is situated. Release by the Department from recapturing the payment may occur if the facility as originally acquired is no longer adequate as a setting to provide the type and level of services now required by older persons in the community, and therefore, the facility, as originally acquired, altered or renovated, will be sold at a price, determined as reasonable by the Department, and that such funds resulting from the sale of the original facility will be used to purchase another facility in the community which meets the standards of this part.

§ 911.24 Notification of action taken on proposals.

Applicants will be notified in writing of the final action taken by the Commissioner on each application. For those applications approved by the Commissioner, this notification shall set forth the amount of funds awarded, and shall constitute for such amounts the incurrence of Federal funds for such proposal on the date of the award.

§ 911.25 Project period.

Except in those instances where an exemption is approved by the Commissioner:

(a) The period of a grant award approved in any fiscal year may not exceed 12 months following the effective date of the "Notice of Grant Awarded" relating to such grant.

(b) All activities relating to the acquisition, alteration or renovation of a facility under this part shall be completed, and the multipurpose program operational, within 12 months following the approval of the grant relating to that activity.

§ 911.26 Payments.

Upon approval of any application for a grant or contract under this part, the Commissioner shall reserve, from any appropriation available therefor, the amount of such grant or contract. The

amount so reserved may be paid in advance or by way of reimbursement, and in such installments consistent with progress in alteration or renovation, as the Commissioner may determine. The Commissioner's reservation of any amount under this section may be amended by him, either upon approval of an amendment of the application or upon revision of the estimated cost of altering or renovating the facility.

Subpart G—Contract Authority**§ 911.27 Authority.**

(a) The Commissioner is authorized to make contracts to carry out the purposes of this part with any agency or organization to pay not to exceed 75 per centum of the costs of such program, subject to the ten per centum maximum payments in any State in any fiscal year.

(b) Any contract under this part shall be entered into in accordance with and shall conform to all of the relevant regulations relating to grants under this title as well as to all other applicable laws, regulations and Department policy.

(c) Payments may be made in advance or by way of reimbursement, and in such installments and on such conditions as the Commissioner may determine.

[FR Doc.76-26338 Filed 9-9-76; 8:45 am]

federal register

FRIDAY, SEPTEMBER 10, 1976



PART III:

**DEPARTMENT OF
HEALTH,
EDUCATION, AND
WELFARE**

Food and Drug Administration



RECODIFICATION

Title 21—Food and Drugs

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

[Docket No. 76N-0320]

Recodification Editorial Amendments

The Food and Drug Administration is in the process of recodifying all of Chapter I of Title 21 of the Code of Federal Regulations, for the purposes of providing orderly development of such regulations, furnishing ample room for expansion in the years ahead, and providing the public and affected industries with regulations that are easy to find, read and understand.

The fourteenth in a series of recodification documents, which reorganize and recodify sections of the general regulations of Subchapter A and the general food regulations under Subchapter B that have applicability to animal drugs, feeds, and related products, is published elsewhere in this issue of the FEDERAL REGISTER. These regulations are now in Parts 501, 503, 507, 508, 509, 564, 570, 571, 573, and 582 of Subchapter E.

To provide uniformity and continuity during the recodification, the Commissioner concludes that the references to the recodified material should be amended at this time.

Due to the complexity and volume of cross-references involved in the recodification of these regulations, if necessary, supplemental documents will be issued at a later date.

Therefore, Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. Section 1.1 is amended by revising paragraph (c) to read as follows:

§ 1.1 General.

(c) The definition of "package" in § 1.1b and of "principal display panel" in §§ 1.7, 201.60, 501.1, 701.10 and 801.60 of this chapter; and the requirements pertaining to uniform location, lack of qualification, and separation of the net quantity declaration in §§ 1.8b(f), 201.62(e), 501.105(f), 701.13(f) and 801.62(e) of this chapter to type size requirements for net quantity declaration in §§ 1.8b(i), 201.62(h), 501.105(i), 701.13(i) and 801.62(h) of this chapter, to initial statement of ounces in the dual declaration of net quantity in §§ 1.8b(j) and (m), 201.62(i) and (k), 501.105(j) and (m), 701.13(j) and (m) and 801.62(i) and (k) of this chapter, to initial statement of inches in declaration of net quantity in §§ 201.62(m), 701.13(o) and 801.62(m) of this chapter, to initial statement of square inches in declaration of net quantity in §§ 201.62(n), 701.13(p) and 801.62(n) of this chapter, to prohibition of certain supplemental net quantity statements in §§ 1.8b(o), 201.62(o), 501.105(o), 701.13(q) and 801.62(o) of this chapter, and to servings representations

in §§ 1.8c and 501.8 are provided for solely by the Fair Packaging and Labeling Act. The other requirements of this part are issued under both the Fair Packaging and Labeling Act and the Federal Food, Drug, and Cosmetic Act, or by the latter act solely, and are not limited in their application by section 10 of the Fair Packaging and Labeling Act.

PART 8—COLOR ADDITIVES

§ 8.301 [Amended]

2. Section 8.301(b) (2) (ii) is amended by changing the reference "§ 121.202" to read "§ 573.380."

§ 8.306 [Amended]

3. Section 8.306(c) (2) (ii) is amended by changing the reference "§ 121.202" to read "§ 573.380."

PART 121—FOOD ADDITIVES

§ 121.1001 [Amended]

4. Section 121.1001(b) is amended by changing the reference "§§ 121.201 and 121.202" to read "§§ 573.380 and 573.400."

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation.

Dated: September 2, 1976.

JOSEPH P. HILE,
Acting Associate Commissioner
for Compliance.

[FR Doc. 76-26298 Filed 9-9-76; 8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Recodification Docket No. 14; Docket No. 76N-0320]

REORGANIZATION AND REPUBLICATION

The Food and Drug Administration is reorganizing and republishing certain sections of the general regulations and the general food regulations that have applicability to animals other than man, effective September 10, 1976.

The Commissioner of Food and Drugs, for the purposes of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations.

This is the fourteenth document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

This material consists of sections of the general regulations under Subchapter A and the general food regulations under Subchapter B. These regulations are being moved to Subchapter E, which will contain all of the regulations on animal drugs, feeds, and related products. Those regulations that pertain to food for human consumption will remain in Sub-

chapter B, which will be recodified in the near future and be limited to just human food. New Parts 501, 503, 507, 508, 509, 564, 570, 571, 573, and 582 are taken from Parts 1, 3, 10, 90, 102, 121, 122, 128b, and the section numbers are keyed to the projected new human food section numbers wherever possible. The texts of the sections are editorially modified to reflect animal applicability.

This document merely recodifies existing regulations and does not represent a change in current requirements for animal feed or pet food.

The following table shows the relationship of the CFR section numbers under Subchapters A and B to this redesignation reflected in Parts 501, 503, 507, 508, 509, 564, 570, 571, 573, and 582:

Old sec.:	New sec.
1.7	501.1
1.8	501.3
1.8a	501.5
1.8b	501.105
1.8c	501.8
1.8d	501.2
1.9	501.15
1.10	501.4
1.10a	501.100
1.10b	501.103
1.12	501.22
1.13	501.17
1.15	501.18
1.16	501.110
3.93	509.15
10.1	564.3
10.2	564.5
10.3	564.8
10.4	564.20
10.5	564.17
10.6	564.12
10.7	564.14
10.8	564.6
90.1	508.3
90.2	508.19
90.3	508.5
90.4	508.7
90.5	508.10
90.6	508.6
90.7	508.12
90.20	508.35
102.1	508.20
102.2	508.22
121.1 except pars. (n) and (o)	570.3
121.2	570.19
121.3	570.30
121.4	570.18
121.5	570.22
121.6	570.20
121.11	570.6
121.40	570.35
121.41	570.38
121.51 except pars. (k) and (l)	571.1
121.51 pars. (k) and (l)	571.100
121.52	571.7
121.53	571.6
121.54	571.102
121.55	571.110
121.56	571.200
121.57	571.203
121.58	571.202
121.59	571.120
121.60	571.204
121.61	571.220
121.62	571.221
121.63	571.222
121.64	571.205
121.65	571.206
121.66	571.208
121.67	571.210
121.68	571.212
121.69	571.214
121.70	571.230
121.71	571.232
121.72	570.15
121.73	571.235

Old sec.	New sec.
121.74	571.130
121.75	570.17
121.101 except table in (d) and (e) through (i)	582.1
121.101(d)	582.1005,
582.1009, 582.1033, 582.1057, 582.1061,	
582.1069, 582.1073, 582.1077, 582.1087,	
582.1091, 582.1095, 582.1099, 582.1125,	
582.1127, 582.1129, 582.1131, 582.1135,	
582.1137, 582.1139, 582.1141, 582.1143,	
582.1155, 582.1165, 582.1191, 582.1193,	
582.1195, 582.1199, 582.1205, 582.1207,	
582.1210, 582.1217, 582.1235, 582.1240,	
582.1275, 582.1320, 582.1324, 582.1355,	
582.1366, 582.1400, 582.1425, 582.1428,	
582.1431, 582.1480, 582.1500, 582.1516,	
582.1540, 582.1585, 582.1613, 582.1619,	
582.1625, 582.1631, 582.1643, 582.1655,	
582.1666, 582.1685, 582.1711, 582.1721,	
582.1736, 582.1742, 582.1745, 582.1748,	
582.1751, 582.1763, 582.1775, 582.1778,	
582.1781, 582.1792, 582.1804, 582.1810,	
582.1901, 582.1973, 582.1975, 582.1978,	
582.2122, 582.2227, 582.2437, 582.2727,	
582.2729, 582.2906, 582.3013, 582.3021,	
582.3041, 582.3081, 582.3089, 582.3109,	
582.3149, 582.3169, 582.3173, 582.3189,	
582.3221, 582.3225, 582.3280, 582.3336,	
582.3490, 582.3616, 582.3637, 582.3640,	
582.3660, 582.3670, 582.3731, 582.3733,	
582.3739, 582.3766, 582.3784, 582.3795,	
582.3798, 582.3845, 582.3862, 582.3890,	
582.4101, 582.4505, 582.4521, 582.4666,	
582.5013, 582.5017, 582.5049, 582.5065,	
582.5118, 582.5145, 582.5159, 582.5191,	
582.5195, 582.5201, 582.5210, 582.5212,	
582.5217, 582.5223, 582.5230, 582.5245,	
582.5250, 582.5252, 582.5260, 582.5271,	
582.5273, 582.5301, 582.5304, 582.5306,	
582.5308, 582.5311, 582.5315, 582.5361,	
582.5370, 582.5375, 582.5381, 582.5406,	
582.5411, 582.5431, 582.5434, 582.5443,	
582.5446, 582.5449, 582.5452, 582.5455,	
582.5458, 582.5461, 582.5464, 582.5470,	
582.5475, 582.5477, 582.5530, 582.5535,	
582.5580, 582.5590, 582.5622, 582.5628,	
582.5634, 582.5650, 582.5676, 582.5695,	
582.5697, 582.5701, 582.5772, 582.5778,	
582.5835, 582.5875, 582.5878, 582.5881,	
582.5890, 582.5892, 582.5915, 582.5920,	
582.5925, 582.5930, 582.5933, 582.5936,	
582.5945, 582.5950, 582.5953, 582.5985,	
582.5988, 582.5991, 582.5994, 582.5997,	
582.6033, 582.6085, 582.6099, 582.6185,	
582.6193, 582.6195, 582.6197, 582.6199,	
582.6203, 582.6215, 582.6219, 582.6285,	
582.6290, 582.6386, 582.6511, 582.6540,	
582.6651, 582.6754, 582.6757, 582.6760,	
582.6769, 582.6778, 582.6787, 582.6789,	
582.6801, 582.6804, 582.6807, 582.6810,	
582.6851, 582.7115, 582.7133, 582.7187,	
582.7255, 582.7330, 582.7333, 582.7339,	
582.7343, 582.7349, 582.7351, 582.7610,	
582.7724	
121.101(e) (1)	582.10
121.101(e) (2)	582.20
121.101(e) (3)	582.30
121.101(e) (4)	582.40
121.101(e) (5)	582.50
121.101(f)	582.80
121.101(g)	582.60
121.102	582.99
121.201	573.400
121.202	573.380
121.203	573.820
121.206	573.500
121.209	573.180
121.219	573.480
121.222	573.1000
121.223	573.700
121.224	573.640
121.229	573.940
121.230	573.420
121.231	573.300
121.234	573.600
121.235	573.800
121.236	573.840
121.239	573.780
121.242	573.680

Old sec.	New sec.
121.246	573.680
121.247	573.580
121.250	573.260
121.261	573.720
121.265	573.320
121.271	573.360
121.272	573.960
121.273	573.900
121.275	573.520
121.277	573.740
121.282	573.560
121.283	573.980
121.284	573.1020
121.285	573.160
121.286	573.620
121.288	573.120
121.295	573.760
121.298	573.440
121.301	573.540
121.302	573.200
121.306	573.280
121.307	573.880
121.313	573.240
121.319	573.140
121.320	573.800
121.322	573.340
121.325	573.920
121.328	573.220
121.329	573.460
122.1	509.3
122.10	509.30
128b.1	507.3
128b.2	507.1
128b.3	507.81
128b.4	507.83
128b.5	507.87
128b.6	507.40
128b.7	507.60
128b.8	507.110
128b.9	507.89
128b.10	507.10

The changes being made are nonsubstantive and editorial; and for this reason, notice and public procedure are not prerequisites to this promulgation. For the convenience of the user, the entire text of Parts 501, 503, 507, 508, 509, 564, 570, 571, 573, and 582 is set forth below.

Dated: September 2, 1976.

JOSEPH P. HILE,
Acting Associate Commissioner
for Compliance.

Therefore, 21 CFR is amended by redesignating animal food provisions under Parts 1 and 3 of Subchapter A and Parts 10, 90, 102, 121, 122, and 128b of Subchapter B as Parts 501, 503, 507, 508, 509, 564, 570, 571, 573, and 582 of Subchapter E—Animal Drugs, Feeds, and Related Products and republished to read as follows:

PART 501—ANIMAL FOOD LABELING

Subpart A—General Provisions

Sec.	
501.1	Principal display panel of package form animal food.
501.2	Information panel of package for animal food.
501.3	Identity labeling of animal food in package form.
501.4	Animal food, designation of ingredients.
501.5	Animal food; name and place of business of manufacturer, packer, or distributor.
501.8	Labeling of animal food with number of servings.
501.15	Animal food; prominence of required statements.
501.17	Animal food labeling warning statements.
501.18	Misbranding of animal food.

Subpart B—Specific Animal Food Labeling Requirements

501.23 Animal foods; labeling of spices, flavorings, colorings, and chemical preservatives.

Subparts C Through E—[Reserved]

Subpart F—Exemptions From Animal Food Labeling Requirements

501.100 Animal food; exemptions from labeling.
501.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.
501.105 Declaration of net quantity of contents when exempt.
501.110 Animal feed labeling; collective names for feed ingredients.

AUTHORITY: Secs. 4, 6, 80 Stat. 1297, 1299, 1300 (15 U.S.C. 1453, 1455) and secs. 403, 602, 701, 52 Stat. 1047-1048 as amended, 1054-1056 as amended (21 U.S.C. 343, 362, 371), unless otherwise noted.

Subpart A—General Provisions

§ 501.1 Principal display panel of package form animal food.

The term "principal display panel" as it applies to food in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring design, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term "area of the principal display panel" means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference;

(c) In the case of any otherwise shaped container, 40 percent of the total surface of the container: *Provided, however, That where such container presents an obvious "principal display panel" such as the top of a triangular or circular package, the area shall consist of the entire top surface. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.*

§ 501.2 Information panel of package for animal food.

(a) The term "information panel" as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel with the following exceptions:

(1) If the part of the label immediately contiguous and to the right of the principal display panel is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.

(2) If the package has one or more alternate principal display panels, the information panel is immediately contiguous and to the right of any principal display panel.

(3) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(b) All information required to appear on the label of any package of food pursuant to §§ 501.4, 501.5, 501.8 and 501.17 shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than 1/16 inch in height unless an exemption pursuant to paragraph (f) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§ 501.15 and 501.105(h) (1) and (2).

(1) Packaged foods are exempt from the type size requirements of this paragraph: *Provided, That:*

(i) The package is designed such that it has a surface area that can bear an information panel and/or an alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 501.1 is less than 10 square inches.

(iii) The label information includes a full list of ingredients in accordance with regulations in this part.

(iv) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than 3/64 inch in height.

(2) Packaged foods are exempt from the type size requirements of this paragraph: *Provided, That:*

(i) The package is designed such that it has a single "obvious principal display panel" as this term is defined in § 501.1 and has no other available surface area for an information panel or alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 501.1 is less than 12 square inches and bears all labeling appearing on the package.

(iii) The label information includes a full list of ingredients in accordance with regulations in this part.

(iv) The information required by paragraph (b) of this section appears on the single, obvious principal display panel in accordance with the provisions of this paragraph (c) except that the type size is not less than 1/32 inch in height.

(3) Packaged foods are exempt from the type size requirements of this paragraph: *Provided, That:*

(i) The package is designed such that it has a total surface area available to bear labeling of less than 12 square inches.

(ii) The label information includes a full list of ingredients in accordance with regulations in this part.

(iii) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than 1/32 inch in height.

(d) All information required to appear on the principal display panel or on the information panel pursuant to this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, any vignettes, design, and other nonmandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required pursuant to any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

(e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 501.4, 501.5, 501.8, and 501.17, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted to the Hearing Clerk in the form established in § 2.65 of this chapter.

(g) If the label of any package of food is too small to accommodate all of the information required by §§ 501.4, 501.5, 501.8, and 501.17, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted to the Hearing Clerk in the form established in § 2.65 of this chapter.

(h) If the label of any package of food is too small to accommodate all of the information required by §§ 501.4, 501.5, 501.8, and 501.17, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted to the Hearing Clerk in the form established in § 2.65 of this chapter.

(i) If the label of any package of food is too small to accommodate all of the information required by §§ 501.4, 501.5, 501.8, and 501.17, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted to the Hearing Clerk in the form established in § 2.65 of this chapter.

§ 501.3 Identity labeling of animal food in package form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to section 401 of the act.

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of § 503.20 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.

(3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation pursuant to false or misleading. The label may, in addition, bear a fanciful name which is part 503 of this chapter), and which complies with all of the applicable re-

quirements of such regulation(s), shall not be deemed to be an imitation.

(4) Nutritional inferiority includes: (i) Any reduction in the content of an essential nutrient that is present in a measurable amount.

(ii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

(f) A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to Part 503 of this chapter.

(Secs. 403, 701(a), 52 Stat. 1047-1048, as amended, 1055; 21 U.S.C. 343, 371(a))

§ 501.4 Animal food; designation of ingredients.

(a) Ingredients required to be declared on the label of a food, including foods that comply with standards of identity that require labeling in compliance with this Part 501, except those exempted by § 501.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 501.2.

(b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

(1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of § 501.22.

(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in this subchapter E, only the ingredients required to be declared by the definition and standard of identity need be listed; or

(ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

(3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as "skim milk" or "nonfat milk".

(4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as "milk".

(5) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "made from cultured skim milk or cultured buttermilk".

(6) Sweetcream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk, and dried sweetcream buttermilk may be declared as "buttermilk".

(7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as "whey".

(8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as "cream".

(9) Butteroil and anhydrous butterfat may be declared as "butterfat".

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as "eggs".

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as "egg whites".

(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as "egg yolks".

(13) A livestock or poultry feed may be declared by a collective name listed in § 501.110 if it is an animal feed within the meaning of section 201(x) of the act and meets the requirements for the use of a collective name as prescribed in § 501.110 for certain feed ingredients.

(14) [Reserved]

(15) When all the ingredients of a wheat flour are declared in an ingredient statement, the principal ingredient of the flour shall be declared by the name(s) specified in §§ 15.1, 15.40, 15.80 and 15.100 of this chapter, i.e., the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is "flour", "white flour", "wheat flour", or "plain flour"; the first ingredient designated in the ingredient list of durum flour is "durum flour"; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole wheat flour is "whole wheat flour", "graham flour", or "entire wheat flour"; and the first ingredient designated in the ingredient list of whole durum wheat flour is "whole durum wheat flour".

(c) When water is added to reconstitute, completely or partially, an ingredient permitted by paragraph (b) of this section to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the un-reconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as "water" in the ingredient statement.

§ 501.5 Animal food; name and place of business of manufacturer, packer, or distributor.

(a) The label of a food in packaged form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such food; such as "Manufactured for _____," "Distributed by _____," or any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, State, and ZIP Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear either on the label or the labeling (including invoice).

(e) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such food was manufactured or packed or is to be distributed, unless such statement would be misleading.

§ 501.8 Labeling of animal food with number of servings.

(a) The label of any package of a food which bears a representation as to the number of servings contained in such package shall bear in immediate conjunction with such statement, and in the same size type as is used for such statement, a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving; however, such statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example, cupfuls, tablespoonfuls, etc.) when such differing term is common to cookery and describes a constant quantity. Such statement may not be misleading in any particular. A statement of the number of units in a package is not in itself a statement of the number of servings.

(b) If there exists a voluntary product standard promulgated pursuant to the procedures found in 15 CFR Part 10 by the Department of Commerce, quantitatively defining the meaning of the term "serving" with respect to a particular food, then any label representation

as to the number of servings in such packaged food shall correspond with such quantitative definition. (Copies of published standards are available upon request from the National Bureau of Standards, Department of Commerce, Washington, DC 20234.)

§ 501.15 Animal food; prominence of required statements.

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 403(f) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 403 (e) or (f) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 403(f) of the act; or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, how-*

ever, That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If any article of labeling (other than a label) contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on such article of labeling.

§ 501.17 Animal food labeling warning statements.

(a) *Self-pressurized containers.* (1) The label of a food packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning:

WARNING.—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Keep out of reach of children.

(2) In the case of products intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence in the warning required by paragraph (a) (1) of this section.

(3) In the case of products packaged in glass containers, the word "break" may be substituted for the word "puncture" in the warning required by paragraph (a) (1) of this section.

(4) The words "Avoid spraying in eyes" may be deleted from the warning required by paragraph (a) (1) of this section in the case of a product not expelled as a spray.

(b) *Self-pressurized containers with halocarbon or hydrocarbon propellants.* (1) In addition to the warning required by paragraph (a) of this section, the label of a food packaged in a self-pressurized container in which the propellant consists in whole or in part of a halocarbon or a hydrocarbon shall bear the following warning:

WARNING.—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

(2) The warning required by paragraph (b) (1) of this section is not required for the following products:

(i) Products expelled in the form of a foam or cream, which contain less than 10 percent propellant in the container.

(ii) Products in a container with a physical barrier that prevents escape of the propellant at the time of use.

(iii) Products of a net quantity of contents of less than 2 ozs that are designed to release a measured amount of product with each valve actuation.

(iv) Products of a net quantity of contents of less than 1/2 oz.

§ 501.18 Misbranding of animal food.

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(c) Among representations in the labeling of a food which render such food misbranded is any representation that expresses or implies a geographical origin of the food or any ingredient of the food except when such representation is either:

(1) A truthful representation of geographical origin.

(2) A trademark or trade name provided that as applied to the article in question its use is not deceptively misdescriptive. A trademark or trade name comprised in whole or in part of geographical words shall not be considered deceptively misdescriptive if it:

(i) Has been so long and exclusively used by a manufacturer or distributor that it is generally understood by the consumer to mean the product of a particular manufacturer or distributor; or

(ii) Is so arbitrary or fanciful that it is not generally understood by the consumer to suggest geographic origin.

(3) A part of the name required by applicable Federal law or regulation.

(4) A name whose market significance is generally understood by the consumer to connote a particular class, kind, type, or style of food rather than to indicate geographical origin.

Subpart B—Specific Animal Food Labeling Requirements

§ 501.22 Animal foods; labeling of spices, flavorings, colorings, and chemical preservatives.

(a) (1) The term "artificial flavor" or "artificial flavoring" means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in §§ 582.60 and 121.1164(b) of this chapter except where these are derived from natural sources.

(2) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed

in Subpart A of Part 582 of this chapter, such as the following:

Allspice	Marjoram
Anise	Mustard flour
Basil	Nutmeg
Bay leaves	Oregano
Caraway seed	Paprika
Cardamom	Parsley
Celery seed	Pepper, black
Chervil	Pepper, white
Cinnamon	Pepper, red
Cloves	Rosemary
Coriander	Saffron
Cumin seed	Sage
Dill seed	Savory
Fennel seed	Star aniseed
Fenugreek	Tarragon
Ginger	Thyme
Horseradish	Turmeric
Mace	

Paprika, tumeric, and saffron or other spices which are also colors, shall be declared as "spice and coloring" unless declared by their common or usual name.

(3) The term "natural flavor" or "natural flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors, include the natural essence or extractives obtained from plants listed in Subpart A of Part 582 of this chapter, and the substances listed in § 121.1163 of this chapter.

(4) The term "artificial color" or "artificial coloring" means any "color additive" as defined in § 8.1(f) of this chapter.

(5) The term "chemical preservative" means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(b) A food which is subject to the requirements of section 403(k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of section 403(k) of the act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of section 403(k) of the act (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(k) of the Act.

(f) A fruit or vegetable shall be exempt from compliance with the requirements of section 403(k) of the act with respect to a chemical preservative applied to the fruit or vegetable as a pesticide chemical prior to harvest.

(g) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, unless it is a flavor for which a standard of identity has been promulgated, in which case it shall be labeled as provided in the standard:

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients, the label either may declare each ingredient by its common or usual name or may state "All flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration." Any flavor ingredient not contained in one of these regulations, and any nonflavor ingredient, shall be separately listed on the label.

(3) In cases where the flavor contains a solely natural flavor(s), the flavor shall be so labeled, e.g., "strawberry flavor," "banana flavor," or "natural strawberry flavor." In cases where the flavor contains both a natural flavor and an artificial flavor, the flavor shall be so labeled, e.g., "natural and artificial strawberry flavor." In cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, e.g., "artificial strawberry flavor."

(h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way:

(1) Spice, natural flavor, and artificial flavor may be declared as "spice," "natural flavor," or "artificial flavor," or any combination thereof, as the case may be.

(2) An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of § 501.100(a) (3).

(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, e.g., powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.

(4) Any salt (sodium chloride) used as an ingredient in food shall be declared by its common or usual name "salt."

(5) Any monosodium glutamate used as an ingredient in food shall be declared by its common or usual name "monosodium glutamate."

(6) Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food may be declared as artificial flavor or artificial smoke flavor. No representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i) (1) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

(2) If the food contains any artificial flavor which simulates, resembles or re-

inforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name(s) of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food and the name of the characterizing flavor shall be accompanied by the word(s) "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(3) Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, except:

(i) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and

(ii) If the finished product contains more than one flavor subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such food.

(iii) If the finished product contains three or more distinguishable characterizing flavors, or a blend of flavors with no primary recognizable flavor, the flavor may be declared by an appropriately descriptive generic term in lieu of naming each flavor.

(4) A flavor supplier shall certify, in writing, that any flavor he supplies which is designated as containing no artificial flavor does not, to the best of his knowledge and belief, contain any artificial flavor, and that he has added no artificial flavor to it. The requirement for such certification may be satisfied by a guarantee under section 303(c)(2) of the act which contains such a specific statement. A flavor used shall be required to make such a written certification only where he adds to or combines another flavor with a flavor which has been certified by a flavor supplier as containing no artificial flavor, but otherwise such user may rely upon the supplier's certification and need make no separate certification. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of 3 years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized officer or employee of the Food and Drug Administration or any other employee acting on behalf of the Secretary of Health, Education, and Welfare. Such certifications are regarded by the

Food and Drug Administration as reports to the government and as guarantees or other undertakings within the meaning of section 301(h) of the act and subject the certifying party to the penalties for making any false report to the government under 18 U.S.C. 1001 and any false guarantee or undertaking under section 303(a) of the act. The defenses provided under section 303(c)(2) of the act shall be applicable to the certifications provided for in this section.

(ii) Wherever possible, the Food and Drug Administration shall verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications.

(iii) Where no person authorized to provide such information is reasonably available at the time of inspection, the certifying party shall arrange to have such person and the relevant materials and records ready for verification as soon as practicable; provided that, whenever the Food and Drug Administration has reason to believe that the supplier or user may utilize this period to alter inventories or records, such additional time shall not be permitted. Where such additional time is provided, the Food and Drug Administration may require the certifying party to certify that relevant inventories have not been materially disturbed and relevant records have not been altered or concealed during such period.

(iv) The certifying party shall provide, to an officer or representative duly designated by the Secretary, such qualitative statement of the composition of the flavor or product covered by the certification as may be reasonably expected to enable the Secretary's representatives to determine which relevant raw and finished materials and flavor ingredient records are reasonably necessary to verify the certifications. The examination conducted by the Secretary's representative shall be limited to inspection and review of inventories and ingredient records for those certifications which are to be verified.

(v) Review of flavor ingredient records shall be limited to the qualitative formula and shall not include the quantitative formula. The person verifying the certifications may make only such notes as are necessary to enable him to verify such certification. Only such notes or such flavor ingredient records as are necessary to verify such certification or to show a potential or actual violation may be removed or transmitted from the certifying party's place of business. Provided, That, where such removal or transmittal is necessary for such purposes the relevant records and notes shall be retained as separate documents in Food and Drug Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding brought pursuant to the act or 18 U.S.C. 1001.

(j) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to § 501.100, bear a

label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., "preservative," "to retard spoilage," "a mold inhibitor," "to help protect flavor" or "to promote color retention."

(Secs. 402, 403, 409, 701(a), 702, 703, 704, 52 Stat. 1046, 1047, 1048-1049 as amended, 1055, 1056-1057 as amended; 21 U.S.C. 342, 343, 348, 371(a), 372, 373, 374.)

Subparts C-E—[Reserved]

Subpart F—Exemptions From Animal Food Labeling Requirements

§ 501.100 Animal food; exemptions from labeling.

(a) The following foods are exempt from compliance with the requirements of section 403(i)(2) of the act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients).

(1) An assortment of different items of food, when variations in the items that make up different packages packed from such assortment normally occur in good packing practice and when such variations result in variations in the ingredients in different packages, with respect to any ingredient that is not common to all packages. Such exemption, however, shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement (in terms that are as informative as practicable and that are not misleading) indicating by name other ingredients which may be present.

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either (i) the labeling of the bulk container plainly in view or (ii) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(i)(2) of the act.

(3) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(a) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(b) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

(c) Substances that are added to a food for their technical or functional ef-

fect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) A food repackaged in a retail establishment is exempt from the following provisions of the act if the conditions specified are met.

(1) Section 403(e) (1) of the act (requiring a statement on the label of the name and place of business of the manufacturer, packer, or distributor).

(2) Section 403(g) (2) of the act (requiring the label of a food which purports to be or is represented as one for which a definition and standard of identity has been prescribed to bear the name of the food specified in the definition and standard and, insofar as may be required by the regulation establishing the standard the common names of the optional ingredients present in the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required by these provisions.

(3) Section 403(i) (1) of the act (requiring the label to bear the common or usual name of the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the common or usual name of the food, or if the common or usual name of the food is clearly revealed by its appearance.

(c) [Reserved]

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (j) and (k) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will ensure, if such specifications are followed, that such food will not be

adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such food from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(e) Conditions affecting expiration of exemptions. (1) An exemption of a shipment or other delivery of a food under paragraph (d) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(2) An exemption of a shipment or other delivery of a food under paragraph (d) (2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by paragraph (d) (2) of this section.

(3) An exemption of a shipment or other delivery of a food under paragraph (d) (2) of this section shall expire:

(i) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(ii) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement as required by such paragraph.

(f) [Reserved]

(g) The label declaration of a harmless marker used to identify a particular manufacturer's product may result in unfair competition through revealing a trade secret. Exemption from the label declaration of such a marker is granted, therefore, provided that the following conditions are met:

(1) The person desiring to use the marker without label declaration of its presence has submitted to the Commissioner of Food and Drugs full information concerning the proposed usage and the reasons why he believes label declaration of the marker should be subject to this exemption; and

(2) The person requesting the exemption has received from the Commissioner of Food and Drugs a finding that the marker is harmless and that the exemption has been granted.

§ 501.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition pursuant to Part 2 of this chapter may issue a proposal to

amend § 501.4 to specify the manner in which an ingredient(s) shall be declared, i.e., by specific or class name, or § 501.100 to exempt an ingredient(s) from the requirements for label declaration.

§ 501.105 Declaration of net quantity of contents when exempt.

(a) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement shall be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, or viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity that is customarily sold by dry measure. If there is a firmly established general consumer usage and trade custom of declaring the contents of a liquid by weight, or a solid, semisolid, or viscous product by fluid measure, it may be used. Whenever the Commissioner determines that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination in the case of a specific packaged food does not facilitate value comparisons by consumers and offers opportunity for consumer confusion, he will by regulation designate the appropriate term or terms to be used for such commodity.

(b) (1) Statements of weight shall be in terms of avoirdupois pound and ounce.

(2) Statements of fluid measure shall be in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall:

(i) In the case of frozen food that is sold and consumed in a frozen state, express the volume at the frozen temperature.

(ii) In the case of refrigerated food that is sold in the refrigerated state, express the volume at 40° F (4° C).

(iii) In the case of other foods, express the volume at 68° F (20° C).

(3) Statements of dry measure shall be in terms of the U.S. bushel of 2.15042 cubic inches and peck, dry quart, and dry pint subdivisions thereof.

(c) When the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, it shall be combined with such statement of weight, measure, or size of the individual units of the foods as will provide such information.

(d) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce

shall be deemed to permit smaller variations than one which does not include such fractions.

(e) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.

(f) The declaration shall appear as a distinct item on the principal display panel, shall be separated (by at least a space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and (by at least a space equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement) from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count (such as "jumbo quart" and "full gallon") that tends to exaggerate the amount of the food in the container. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: *Provided*, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part.

(g) The declaration shall accurately reveal the quantity of food in the package exclusive of wrappers and other material packed therewith; provided that in the case of foods packed in containers designed to deliver the food under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed. The propellant is included in the net quantity declaration.

(h) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

(1) The ratio of height to width (of the letter) shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide).

(2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter "o" or its equivalent that shall meet the minimum standards.

(3) When fractions are used, each component numeral shall meet one-half the minimum height standards.

(i) The declaration shall be in letters and numerals in a type size established

in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than $\frac{1}{16}$ inch in height on packages the principal display panel of which has an area of 5 square inches or less.

(2) Not less than $\frac{1}{8}$ inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches.

(3) Not less than $\frac{3}{16}$ inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(4) Not less than $\frac{1}{4}$ inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than $\frac{1}{2}$ inch in height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraph (i) (1) through (4) of this section shall be increased by $\frac{1}{16}$ of an inch.

(j) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (1 pound or 1 pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (see examples set forth in paragraph (m) (1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples in paragraph (m) (3) and (4) of this section).

(2) If the net quantity of contents declaration appears on a random package, that is a package which is one of a lot, shipment, or delivery of packages of the same consumer commodity with varying weights and with no fixed weight pattern, it may, when the net weight exceeds 1 pound, be expressed in terms of pounds and decimal fractions of the pound carried out to not more than two decimal places. When the net weight does not exceed 1 pound, the declaration on the random package may be in decimal fractions of the pound in lieu of ounces (see example in paragraph (m) (5) of this section).

(3) The declaration may appear in more than one line. The term "net weight" shall be used when stating the net quantity of contents in terms of weight. Use of the terms "net" or "net contents" in terms of fluid measure or numerical count is optional. It is sufficient to distinguish *avoirdupois* ounce from fluid ounce through association of terms; for example, "Net wt. 6 oz." or "6 oz. Net wt." and "6 fl. oz." or "Net contents 6 fl. oz."

(k) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of fluid measure, it shall be expressed in the largest whole unit (gallons followed by common or decimal fraction of a gallon or by the next smaller whole unit or units (quarts, or quarts and pints)) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see paragraph (m) (6) of this section).

(l) [Reserved]

(m) Examples:

(1) A declaration of $1\frac{1}{2}$ pounds weight shall be expressed as "Net Wt. 24 oz. (1 lb. 8 oz.)," "Net Wt. 24 oz. ($1\frac{1}{2}$ lb.)," or "Net Wt. 24 oz. (1.5 lb.)."

(2) A declaration of $\frac{3}{4}$ pound *avoirdupois* weight shall be expressed as "Net Wt. 12 oz."

(3) A declaration of 1 quart liquid measure shall be expressed as "Net 32 fl. oz. (1 qt.)."

(4) A declaration of $1\frac{3}{4}$ quarts liquid measure shall be expressed as "Net contents 56 fluid ounces (1 quart $1\frac{3}{4}$ pints)" or as "Net 56 fluid oz. (1 qt. 1 pt. 8 oz.)," but not in terms of quart and ounce such as "Net 56 fluid oz. (1 quart 24 ounces)."

(5) On a random package, declaration of $\frac{3}{4}$ pound *avoirdupois* may be expressed as "Net Wt. 75 lb."

(6) A declaration of $2\frac{1}{2}$ gallons liquid measure shall be expressed as "Net contents $2\frac{1}{2}$ gallons," "Net contents 2.5 gallons," or "Net contents 2 gallons 2 quarts" and not as "2 gallons 4 pints".

(n) For quantities, the following abbreviations and none other may be employed (periods and plural forms are optional):

weight wt.	pint pt.
ounce oz.	quart qt.
pound lb.	fluid fl.
gallon gal.	

(o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents; provided, that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the food contained in the package; for example, "jumbo quart" and "full gallon". Dual or combination declarations of net quantity of contents as provided for in paragraphs (a), (c), and (j) of this section (for example, a combination of net weight plus numerical count, net contents plus dilution directions of a concentrate, etc.) are not regarded as supplemental net quantity statements and may be located on the principal display panel.

(p) A separate statement of the net quantity of contents in terms of the metric system is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or

measure may also appear on the principal display panel or on other panels.

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

(r) [Reserved]

(s) On a multiunit retail package, a statement of the quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and, in parentheses, the total quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by paragraph (j) (1) of this section. A multiunit retail package may thus be properly labeled: "6-16 oz. bottles—(96 fl. oz.)" or "3-16 oz. cans—(net wt. 48 oz.)". For the purposes of this section, "multiunit retail package" means a package containing two or more individually packaged units of the identical commodity and in the same quantity, intended to be sold as part of the multiunit retail package but capable of being individually sold in full compliance with all requirements of the regulations in this part. Open multiunit retail packages that do not obscure the number of units nor prevent examination of the labeling on each of the individual units are not subject to this paragraph if the labeling of each individual unit complies with the requirements of paragraphs (f) and (i) of this section.

(t) Where the declaration of net quantity of contents is in terms of net weight and/or drained weight or volume and does not accurately reflect the actual quantity of the contents or the product falls below the applicable standard of fill of container because of equipment malfunction or otherwise unintentional product variation, and the label conforms in all other respects to the requirements of this chapter (except the requirement that food falling below the applicable standard of fill of container shall bear the general statement of substandard fill specified in § 564.14(b) of this chapter), the mislabeled food product, including any food product that fails to bear the general statement of substandard fill specified in § 564.14(b) of this chapter, may be sold by the manufacturer or processor directly to institutions operated by Federal, State or local governments: *Provided, That:*

(1) The purchaser shall sign a statement at the time of sale stating that he is aware that the product is mislabeled to include acknowledgement of the nature and extent of the mislabeling, e.g., "Actual net weight may be as low as ____% below labeled quantity" and

that any subsequent distribution by him of said product except for his own institutional use is unlawful. This statement shall be kept on file at the principal place of business of the manufacturer or processor for 2 years subsequent to the date of shipment of the product and shall be available to the Food and Drug Administration upon request.

(2) The product shall be labeled on the outside of its shipping container with the statement(s):

(i) When the variation concerns net weight and/or drained weight of volume—"Product Mislabeled. Actual net weight (drained weight or volume where appropriate) may be as low as ____% below labeled quantity. This Product Not for Retail Distribution", the blank to be filled in with the maximum percentage variance between the labeled and actual weight or volume of contents of the individual packages in the shipping container, and

(ii) When the variation is in regard to a fill of container standard—"Product Mislabeled. Actual fill may be as low as ____% below standard of fill. This Product Not for Retail Distribution."

(3) The statements required by paragraph (t) (2) (i) and (ii) of this section, which may be consolidated where appropriate, shall appear prominently and conspicuously as compared to other printed matter on the shipping container and in boldface print or type on a clear, contrasting background in order to render them likely to be read and understood by the purchaser under ordinary conditions of purchase.

(Sec. 5(a), 80 Stat. 1298; 15 U.S.C. 1454)

§ 501.110 Animal feed labeling; collective names for feed ingredients.

(a) An animal feed shall be exempt from the requirements of section 403(i) (2) of the act with respect to its label bearing the common or usual names of the animal feed ingredients listed in paragraph (b) of this section under the following prescribed conditions:

(1) The animal feed is intended solely for livestock and poultry.

(2) The label of the animal feed bears the collective name(s) prescribed in paragraph (b) of this section in lieu of the corresponding common or usual names of the individual feed ingredients contained therein.

(3) The label of the animal feed otherwise conforms to the requirements of section 403(i) (2) of the act.

(4) The ingredients of any feed listed in paragraph (b) of this section neither contain nor are food additives as defined in section 201(s) of the act unless provided for by and in conformity with applicable regulations established pursuant to section 409 of the act.

(b) Each collective name referred to in this paragraph may be used for the purpose of labeling where one or more of the ingredients listed for that collective name are present. The animal feed ingredients listed under each of the collective names are the products defined by the Association of American Feed Control Officials. The collective names are as follows:

(1) "Animal protein products" include one or more of the following: Animal products, marine products, and milk products.

(2) "Forage products" include one or more of the following: Alfalfa meals, entire plant meals, hays, and stem meals.

(3) "Grain products" include one or more of the following: Barley, grain sorghums, malze (corn), oats, rice, rye, and wheat.

(4) "Plant protein products" include one or more of the following: Algae meals, coconut meals (copra), cottonseed meals, guar meal, linseed meals, peanut meals, safflower meals, soybean meals, sunflower meals, and yeasts.

(5) "Processed grain byproducts" include one or more of the following: Brans, brewers dried grains, distillers grains, distillers solubles, flours, germ meals, gluten feeds, gluten meals, grits, groats, hominy feeds, malt sprouts, middlings, pearled, polishings, shorts, and wheat mill run.

(6) "Roughage products" include one or more of the following: Cobs, hulls, husks, pulps, and straws.

(Secs. 4, 6, 80 Stat. 1297, 1299, 1300 (15 U.S.C. 1453, 1455) and secs. 403, 602, 701, 32 Stat. 1047-1048, 1054-1056 as amended (21 U.S.C. 343, 352, 362, 371).)

PART 503—COMMON OR USUAL NAMES FOR NONSTANDARDIZED ANIMAL FOODS

Sec.

503.20 General principles.

503.22 Petitions.

AUTHORITY: Secs. 201(n), 403, 701(a), 52 Stat. 1041 as amended, 1047-48 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a)).

§ 503.20 General principles.

(a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) ---- percent (or %) ----" or "---- percent (or %) ----" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words "---- percent (or %) ----" shall appear following or directly below the word "containing" (or "contains"), or directly below the part of the common or usual name of the food required by paragraph (a) of this section when the word "containing" (or "contains") is not used, in easily legible bold-face print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

(c) The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. The following requirements shall apply unless modified by a specific regulation in this part.

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words "containing (or contains) ----" or "containing (or contains) no ----" or "no ----" or "does not contain ----" with the blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under paragraph (c)(1) and/or (2) of this section shall appear following or directly below the part of the common or usual

name of the food required by paragraphs (a) and (b) of this section, in easily legible bold face print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the alternatives established under paragraph (b)(2)(i) and (ii) of this section.

(d) A common or usual name of a food may be established by common usage or by establishment of a regulation in this part, in a standard of identity, or in other regulations in this chapter.

§ 503.22 Petitions.

(a) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under this part, a regulation prescribing a common or usual name for a food. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 2.65 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

(b) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative (e.g., a smaller type size). A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted to the office of the Hearing Clerk in the form set forth in § 2.65 of this chapter.

PART 507—THERMALLY PROCESSED LOW-ACID ANIMAL FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Subpart A—General Provisions

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507.1	Current good manufacturing practice.
507.3	Definitions.
507.10	Personnel.

Subpart B—[Reserved]

Subpart C—Equipment

507.40	Equipment and procedures.
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Subpart D—Control of Components, Food Product Containers, Closures, and In-Process Materials

507.60	Containers.
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Subpart E—Production and Process Controls

507.81	Product preparation.
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507.87	Operations in the thermal processing room.
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Subpart F—Records and Reports

507.110	Processing and production records.
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AUTHORITY: Secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(4), 371(a)).

Subpart A—General Provisions

§ 507.1 Current good manufacturing practice.

The criteria in §§ 507.10 through 507.110 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or

packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

§ 507.3 Definitions.

(a) "Aseptic processing and packaging" means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetic sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) "Bleeders" means openings used to remove air, that enters with steam, from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) "Coming-up-time" means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) "Commercial processor" shall include any person engaged in commercial custom, and so-called sportsman processing or institutional processing of food.

(e) "Commercial sterility" of food means the condition achieved by application of heat which renders such food free of viable forms of microorganisms having public health significance, as well as any microorganisms of nonhealth significance capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution. "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment which renders such equipment and containers free of viable forms of microorganisms having public health significance as well as any microorganisms of nonhealth significance capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) "Flame sterilizer" means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, over gas flames to achieve sterilization temperatures. A holding period in a heated section may follow the initial heating period.

(g) "Headspace, gross" is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

(h) "Headspace, net" of a container having a double seam, such as a can, is the vertical distance between the level of the product (generally the liquid surface) in the upright rigid container and the inside surface of the lid.

(i) "Hermetically sealed container" means a container which is designed and intended to be secure against the entry of microorganisms and to maintain the commercial sterility of its contents after processing.

(j) "Incubation" means the holding of a sample(s) at a specified temperature for a specified period of time before examination.

(k) "Initial temperature" means the average temperature of the contents of the coldest container to be processed at the time the sterilizing cycle begins, as determined after thorough stirring or shaking of the filled and sealed container.

(l) "Lot" means the product produced during the period of time indicated by a specific code.

(m) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH value greater than 4.6 and a water activity greater than 0.85 and also includes any normally low-acid fruits, vegetables, or vegetable products in which the purpose of thermal processing the pH value is reduced by acidification. Tomatoes, pears, and pineapples, or the juices thereof, having a pH of less than 4.7 and figs having a pH of 4.9 or below shall not be classed as low-acid foods.

(n) "Minimum thermal process" means the application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.

(o) "Retort" means any closed vessel or other equipment used for the thermal processing of foods.

(p) "Scheduled process" means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. This process may be in excess of that necessary to ensure destruction of microorganisms of public health significance.

(q) "Shall" and "should." As used in this part, "shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(r) "Vents" means openings controlled by gate, plug cock, or other adequate valves used for the elimination of air during the venting period.

(s) "Water activity" or "a_w" means the vapor pressure of the food product divided by the vapor pressure of pure water under identical conditions of pressure and temperature.

§ 507.10 Personnel.

All operators of retorts, processing systems, and aseptic processing and packaging systems, and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, processing systems operations, aseptic processing and packaging systems operations, and container closure inspections, and has been identified by that school as having satisfactorily completed the prescribed course of instruction.

Subpart B—[Reserved]

Subpart C—Equipment

§ 507.40 Equipment and procedures.

(a) *Equipment and procedures for pressure processing in steam in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer with a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a 3/4-inch diameter opening, and shall be equipped with a 1/16 inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each still retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with a steam controller to maintain the retort temperature. This

may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.

(6) *Crate supports.* A bottom crate support shall be employed in vertical still retorts. Baffle plates shall not be used in the bottom of still retorts.

(7) *Steam spreaders.* Steam spreaders, which are perforated or other style continuations of the steam line inside the retort, should not be larger than the steam inlet line. Horizontal still retorts shall be equipped with steam spreaders that extend along the bottom for the length of the retort; the perforations should be along the top 90° of this pipe. Horizontal still retorts over 30 feet long should have two steam inlets connected to the spreader. In vertical still retorts the steam spreaders, if used, should be in the form of a cross with the perforations along the top or sides of the pipe. The number of perforations in spreaders for both horizontal and vertical still retorts should be such that the total cross-sectional area of the perforations is equal to 1½ to 2 times the cross-sectional area of the steam inlet line.

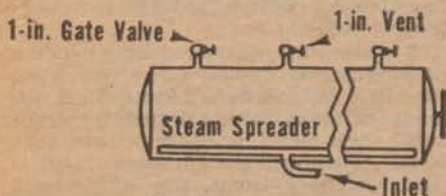
(8) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the coming-up-time. For horizontal retorts, bleeders shall be located within approximately 1 foot of each end; additional bleeders shall be located not more than 8 feet apart along the top. Vertical retorts shall have at least one bleeder opening located in that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to ensure removal of condensate. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If dividers are used between the layers of containers, they should be perforated as above. When there is stratification of the product in the containers, the containers should be processed in such a position that the plane of stratification is vertical.

(10) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by

gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or other adequate type valve. The retort manifold shall be of a size such that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached. Retorts using air for pressure cooling shall be equipped with a ball or globe valve or suitable valve and piping arrangement on the air line to prevent air leakage into the retort during processing. Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts are given in paragraph (a) (10) (i) (a) through (d) and (ii) (a) and (b) of this section. Other installations and operating procedures which deviate from the above specifications may be used, provided that there is evidence that they accomplish adequate venting of air.

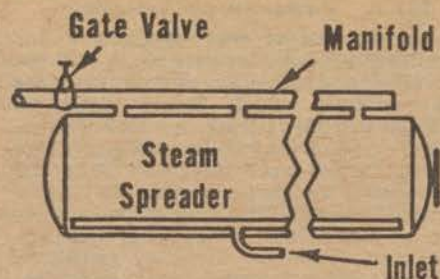
(i) *Venting horizontal retorts.* (a) Venting through multiple 1-inch vents discharging directly to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length, equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than 2½ feet from ends of retort.

Venting method. Vent valves should be wide open for at least 5 minutes and to at least 225° F, or at least 7 minutes and to at least 220° F.

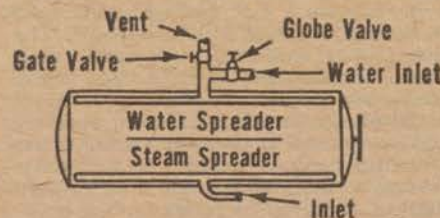
(b) Venting through multiple 1-inch vents discharging through a manifold to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length; end vents not over 2½ feet from ends of retort; size of manifold—for retorts less than 15 feet in length, 2½ inches; for retorts 15 feet and over in length, 3 inches.

Venting method. Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225° F, or for at least 8 minutes and to at least 220° F.

(c) Venting through water spreaders.

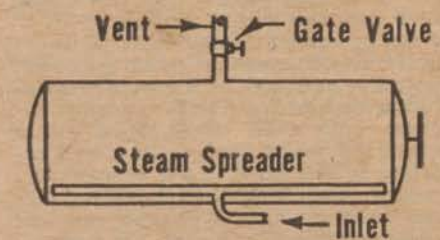


Size of water inlet, vent pipe, and vent valve. For retorts less than 15 feet in length, 2 inches; for retorts 15 feet and over in length, 2½ inches.

Size of water spreader. For retorts less than 15 feet in length, 1½ inches; for retorts 15 feet and over in length, 2 inches.

Venting method. Water spreader vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 225° F, or for at least 7 minutes and to at least 220° F.

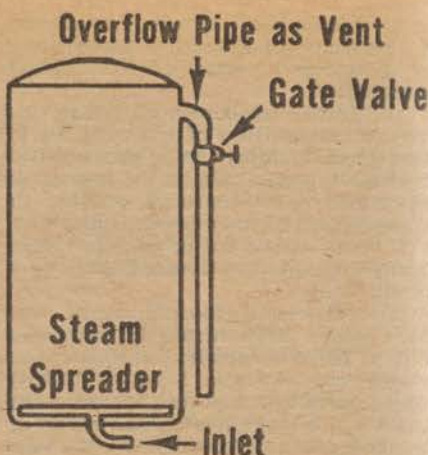
(d) Venting through a single 2½-inch top vent (for retorts not exceeding 15 feet in length).



Specifications. A 2½-inch vent equipped with a 2½-inch gate or plug cock valve and located within 2 feet of the center of the retort.

Venting method. Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220° F.

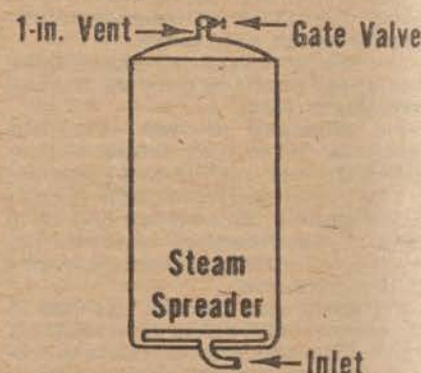
(ii) *Venting vertical retorts.* (a) Venting through a 1½-inch overflow.



Specifications. A 1½-inch overflow pipe equipped with a 1½-inch gate or plug cock valve and with not more than 6 feet of 1½-inch pipe beyond the valve before break to the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218° F, or for at least 5 minutes and to at least 215° F.

(b) Venting through a single 1-inch side or top vent.



Specifications. A 1-inch vent in lid or top side, equipped with a 1-inch gate or plug cock valve and discharging directly into the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 230° F, or for at least 7 minutes and to at least 220° F.

(11) *Critical factors.* (i) Where maximum drained weight is specified in the scheduled process it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(b) *Equipment and procedures for pressure processing in water in still retorts.*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length or a temperature range of not more than 150° F on a scale at least 9 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts this entry should be made in the side at the center, and the thermometer bulbs shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the thermometer bulbs shall extend directly into the water a minimum of at least 2 inches without a separable well or sleeve. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each still retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The recording thermometer bulb should be located adjacent to the bulb of the mercury-in-glass thermometer except in the case of a vertical retort equipped with a combination recorder-controller. In such vertical retorts the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts the temperature recorder-control bulb shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement upon the control bulb.

(3) *Pressure gages.* (4) Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 lbs or less, should be connected

to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(ii) An adjustable pressure relief, or control valve of a capacity sufficient to prevent undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.

(4) *Steam introduction.* The distribution of steam in the bottom of the retort shall be accomplished in a manner adequate to provide uniform heat distribution throughout the retort. In vertical retorts, uniform steam distribution can be achieved by any of several methods. In horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.

(5) *Crate supports.* A bottom crate support shall be employed in vertical still retorts. Baffle plates shall not be used in the bottom of the retort. Centering guides should be installed so as to ensure that there be about 1½ inches clearance between the side wall of the crate and the retort wall.

(6) *Stacking equipment.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If divider plates are used between the layers of containers, they should be perforated as above.

(7) *Drain valve.* A nonclogging, water-tight valve shall be used. Screens should be installed over all drain openings.

(8) *Water level indicator.* There shall be a means of determining the water level in the retort during operation (e.g., by using a gage water glass or petcock(s)). Water shall cover the top layer of containers during the entire coming-up-time and processing periods and should cover the top layer of containers during the cooling periods.

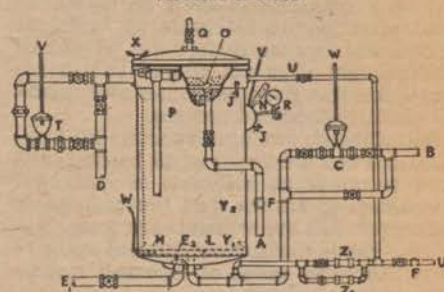
(9) *Air supply and controls.* In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system. Air or water circulation shall be maintained continuously during the coming-up-time, processing, and cooling periods; if air is used to promote circulation it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

(10) *Cooling water supply.* In vertical retorts the cooling water should be introduced at the top of the retort between the water and container levels; in horizontal retorts the cooling water should be introduced into the suction side of the pump. A check valve should be included in the cooling water line.

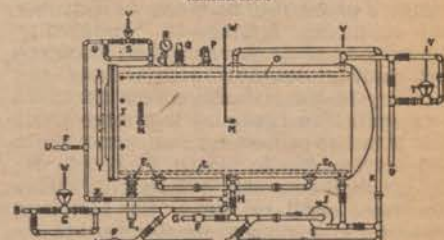
(11) *Retort headspace.* The headspace necessary to control the air pressure should be maintained between the water level and the top of the retort shell.

(12) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the following diagrams or be equivalent.

Vertical Retorts



Horizontal Retorts



LEGEND FOR VERTICAL AND HORIZONTAL STILL RETORTS

- A—Water line.
- B—Steam line.
- C—Temperature control.
- D—Overflow line.
- E—Drain line.
- F—Screens.
- G—Check valves.
- H—Line from hot water storage.
- I—Suction line and manifold.
- J—Circulating pump.
- K—Petcocks.
- L—Recirculating line.
- M—Steam distributor.
- N—Temperature controller bulb.
- O—Thermometer.
- P—Water spreader.
- Q—Safety valve.
- R—Vent valve for steam processing.
- S—Pressure gage.
- T—Inlet air control.
- U—Pressure control.
- V—Air line.
- W—To pressure control instrument.
- X—To temperature control instrument.
- Y—Wing nuts.
- Z—Crate support.
- Y1—Crate guides.
- Z1—Constant flow orifice valve.
- Z2—Constant flow orifice valve used during cook.

(13) *Water circulation.* When a water circulating system is used for heat distribution it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed and should have an aggregate area not greater than the cross section area of the outlet line from the pump. The suction outlets should be protected with nonclog-

ging screens to keep debris from entering the circulating system. The pump shall be equipped with a pilot light or other signaling device to warn the operator when it is not running, and with a bleeder to remove air when starting operations.

(14) *Critical factors.* (i) Where maximum drained weight is specified in the scheduled process it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(c) *Equipment and procedures for pressure processing in steam in continuous agitating retorts.* (1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a 3/4-inch diameter opening, and shall be equipped with a 1/8-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to

the shell. Each temperature recorder bulb well shall have a 1/8-inch or larger bleeder opening emitting steam continuously during the processing period.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be 1/8-inch or larger and shall be wide open during the entire process, including the coming-up-time. Bleeders shall be located within approximately 1 foot of each end; additional bleeders shall be located not more than 8 feet apart along the top of the retort. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time a speed change is made, and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided.

(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall either be operated as a still retort, with all containers being given a full still retort process before the retort is cooled, or the retort shall be cooled promptly and all containers shall be either reprocessed, repacked and reprocessed, or discarded.

(i) Any containers in the retort intake valve of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.

(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records

required in this chapter. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort at the time of stopping and cooling shall be entered on the production records.

(9) *Temperature drop.* If the temperature of the continuous retort drops below the temperature specified in the scheduled process while containers are in the retort, the retort reel shall be stopped promptly. An automatic device should be used to stop the reel when the temperature drops below the specified process temperature. Before the reel is restarted, all containers in the retort shall be given a complete still retort process if the temperature drop was 10° F or more below the specified temperature. Alternatively, container entry to the retort shall be stopped and the reel shall be restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or discarded. Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of emptying the retort is followed, the subsequent handling methods used for the containers in the retort at the time of the temperature drop shall be entered on the production records. If the temperature drop was less than 10° F, an authorized emergency still process approved by a qualified person(s) having expert knowledge of thermal processing requirements may be used before restarting the retort reel. Alternatively, container entry to the retort shall be stopped and an authorized emergency agitating process may be used before container entry to the retort is restarted. If any emergency process and procedure is utilized, no containers shall enter the retort during this time and the process and procedures used shall be entered on the production records.

(10) *Critical factors.* The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. Measurements of these critical factors shall be made and recorded at intervals of sufficient frequency to ensure that they are as specified in the scheduled process. All measurements and recordings of critical

factors should be made at intervals not to exceed 15 minutes.

(d) *Equipment and procedures for pressure processing in steam in discontinuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer*. Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a 3/4-inch diameter opening, and shall be equipped with a 1/8-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. Thermometers shall be installed where they can be accurately and easily read. A thermometer with a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device*. There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a 1/8-inch or larger bleeder opening emitting steam continuously during the processing period.

(3) *Pressure gages*. Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller*. Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Bleeders*. Bleeders, except those for thermometer wells, shall be 1/8 inch

or larger and shall be wide open during the entire process, including the coming-up-time. Bleeders shall be located within approximately 1 foot of each end; additional bleeders shall be located not more than 8 feet apart along the top of the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to ensure removal of condensate. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Venting and condensate removal*. The air in each retort shall be removed before processing is started. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for continuing drainage of condensate during the retort operation.

(7) *Retort speed timing*. The rotational speed of the retort shall be specified in the scheduled process. The rotational speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided.

(8) *Critical factors*. The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. Measurements of these critical factors shall be made and recorded at intervals of sufficient frequency to ensure that they are as specified in the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(e) *Equipment and procedures for pressure processing in water in discontinuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer*. Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for

accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device*. There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell.

(3) *Pressure gages*. Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller*. Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Retort speed timing*. The rotational speed of the retort shall be specified in the scheduled process. The rotational speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided.

(6) *Air supply and controls*. Means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.

(7) *Critical factors*. The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is

as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. Measurements of these critical factors shall be made and recorded at intervals of sufficient frequency to ensure that they are as specified in the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(1) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—(1) *Indicating mercury-in-glass thermometer*. Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. The thermometer shall be located in the steam dome near the steam-water interface. Where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a mercury-in-glass thermometer shall be located in each hydrostatic water leg in a position near the bottom automatic recorder so that it can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device*. There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch, within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the steam dome or in a well attached to the dome. Temperature recorder bulb wells shall have a 1/16-inch or larger bleeder opening emitting steam

continuously during the entire processing period. Additional temperature recorder bulbs shall be installed in the hydrostatic water legs if the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs.

(3) *Recording of temperatures*. Temperatures indicated by the mercury-in-glass thermometer or thermometers shall be entered on a suitable form during processing operations. Temperatures shall be recorded by an accurate automatic recorder or recorders at the following points:

(i) In the steam chamber between the steam-water interface and the lowest container position.

(ii) Near the top and the bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the legs.

(4) *Venting*. Before the start of processing operations, the retort steam chamber or chambers shall be vented to ensure removal of air.

(5) *Bleeders*. Bleeder openings 1/4-inch or larger shall be located at the end of the steam chamber or chambers opposite from the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the coming-up-time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Retort speed*. The speed of the container conveyor chain shall be specified in the scheduled process and shall be determined and recorded at the start of processing and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified. The speed should be determined and recorded every 4 hours. An automatic device should be used to stop the chain when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided.

(7) *Critical factors*. (i) Where maximum drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Minimum closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(g) *Aseptic processing and packaging systems*—(1) *Product sterilizer*—(i) *Equipment*—(a) *Temperature indicating device*. Each product sterilizer shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length, or an equivalent temperature indicating device, such as a thermocouple-recorder. The scale divisions or chart graduations of the temper-

ature indicating device shall be no more than 2° F within the range of 10° F of the product sterilization operating range. The device shall be installed in the product at the holding tube outlet between the holding tube and the inlet to the cooler. The temperature indicating device shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure its accuracy. The device shall be installed so that it can be accurately and easily read. A thermometer that has a divided mercury column or a device that deviates more than 1° F from the standard shall be repaired or replaced. The temperature indicating device shall be the reference instrument for indicating the processing temperature.

(b) *Temperature recording device*. There shall be an accurate temperature recording device on each product pre-sterilizer. The temperature sensor shall be located in the presterilized product at the holding tube outlet between the holding tube and the inlet of the cooler. The recording device shall be adjusted to agree with a known accurate standard mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The recording device shall not deviate more than 1° F from the standard thermometer; it shall be installed so that it can be accurately and easily read. The recording chart graduations shall not exceed 2° F within a range of 10° F of the desired product sterilization temperature. The chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature.

(c) *Temperature recorder-controller*. An accurate temperature recorder-controller shall be located in the product sterilizer at the final heater outlet. It shall be capable of assuring that the desired product sterilization temperature is maintained. The chart graduations shall not exceed 2° F within a range of 10° F of the desired product sterilization temperature.

(d) *Product-to-product regenerators*. Where a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system. It shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to ensure that any leakage in the regenerator will be from the sterilized product into the unsterilized product.

(e) *Differential pressure recorder-controller*. Where a product-to-product regenerator is used, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 2 pounds per square inch on a working scale of not more than 20 pounds per square inch per inch. The controller shall be tested for accuracy against a known accurate standard pressure indicator, upon installation and at least once every

3 months of operation thereafter or more frequently as may be necessary to ensure its accuracy. One pressure sensor shall be installed at the sterilized product regenerator outlet, and the other pressure sensor shall be installed at the unsterilized product regenerator inlet.

(f) *Metering pump.* A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized speed changes shall be provided.

(g) *Product holding tube.* The product sterilizing holding tube shall be designed to give continuous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion between the product inlet and the product outlet can be heated, and it shall be sloped upward at least 0.25 inch per foot.

(ii) *Operation—(a) Startup.* Prior to the start of aseptic processing operations, the product sterilizer shall be brought to a condition of commercial sterility.

(b) *Temperature drop in product sterilizing holding tube.* When product temperature in the holding tube drops below the temperature specified in the scheduled process, the product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before flow is resumed to the filler.

(c) *Loss of proper pressures in the regenerator.* Where a regenerator is used the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 1 lb. per square in, greater than the pressure of unsterilized product in the regenerator. Product flow to the filler shall not be resumed until the cause of the improper pressure relationships in the regenerator has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

(d) *Records.* Readings at the following points shall be observed and recorded at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process: Temperature indicating device in holding tube outlet; temperature recorder in holding tube outlet; temperature recorder-controller at final heater outlet; differential pressure recorder-controller, if a product-to-product regenerator is used; and product flow rate as established by the metering pump or as determined by filling and closing rates. Such measurements and recordings should be made at intervals not to exceed 1 hr.

(2) *Container sterilizing, filling, and closing operation—(i) Equipment—(a) Recording device.* The container and closure sterilization system and product filling and closing system shall be instrumented to show that commercial sterility is being achieved. Automatic recording devices shall be used to record, where applicable, the sterilization media flow rates and/or temperatures. Where a batch system is used for container sterilization, the sterilization conditions shall be recorded.

(b) *Timing method(s).* A method(s) shall be used either to give the retention

time of containers, and closures if applicable, in the sterilizing environment as specified in the scheduled process, or to control the sterilization cycle at the rate as specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided.

(ii) *Operation—(a) Startup.* Prior to the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

(b) *Loss of sterility.* In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

(c) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates and/or temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.

(3) *Incubation.* Incubation tests shall be conducted on a representative sample of containers of product from each code; records of the tests shall be maintained.

(h) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on the conveyor shall be provided. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(i) *New systems.* The development of new systems for the thermal processing of low-acid foods in hermetically sealed containers shall conform to the applicable requirements of this part and shall

ensure that the methods and controls used for the manufacture, processing, and/or packing of such foods are operated or administered in a manner adequate to achieve commercial sterility.

Subpart D—Controls of Components, Food Product Containers, Closures, and In-Process Materials

§ 507.60 Containers.

(a) *Closures.* Regular observations shall be maintained during production runs for gross closure defects. Any such defects shall be recorded, and corrective action shall be taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used, and shall record his observations. Such measurements and recordings should be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closure machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. Where irregularities are found, the corrective action shall be recorded.

(1) *Teardown examinations* for double seam cans shall be performed by a qualified individual and the results therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seaming station to ensure maintenance of seam integrity. Such examinations and recordings should be made at intervals not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective action taken, if any, shall be noted.

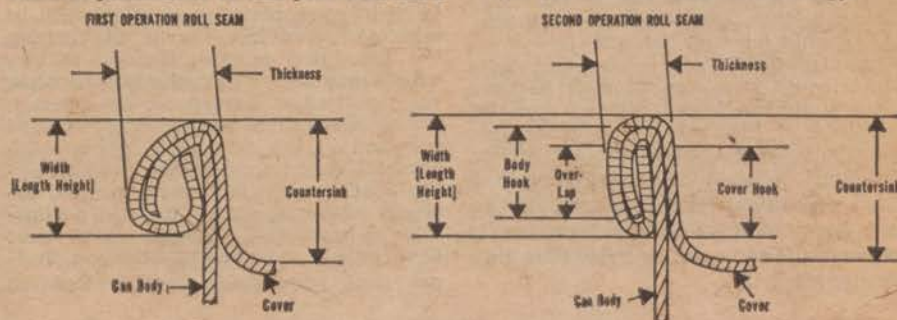
(i) *Required and optional can seam measurements:*

Required	Optional
Cover hook.	Overlap (by calculation).
Body hook.	Countersink.
Width (length, height).	Thickness.
Tightness (observation for wrinkle).	

(b) *Seam scope or projector:*

Required	Optional
Body hook.	Width (length, height).
Overlap.	Cover hook.
Tightness (observation for wrinkle).	Countersink.
	Thickness.

(c) *Can double seam terminology:*



(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120° apart, excluding the side seam.

(iii) Overlap length can be calculated by the following formula:

The theoretical overlap length =
 $CH + BH + T - W$ where
 CH = cover hook
 BH = body hook
 T = cover thickness, and
 W = seam width (height, length)

(2) For closures other than double seams, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b) *Cooling.* Container cooling water should be chlorinated as necessary by the processor so that there is a measurable free chlorine residual at the water discharge point of the container cooler. Other safe chemical or physical treatment which is equivalent to chlorination in its bactericidal effect may be used. Where pressure cooling is utilized, adequate pressure should be maintained for a time sufficient to prevent permanent distortion of the container.

(c) *Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code which shall be permanently visible to the naked eye. Where the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, provided that the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: Intervals of every 4 to 5 hours; personnel shift changes; or batches, provided the containers comprising such batch do not extend over a period of more than one personnel shift.

(d) *Postprocess handling.* Where cans are handled on belt conveyors, such conveyors should be so constructed as to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc., should be replaced with new non-porous material. All tracks and belts which come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. Automatic equipment used in handling filled containers should be so designed and operated in such a manner as to preserve the can seam or other container closure integrity.

Subpart E—Production and Process Controls

§ 507.81 Product preparation.

(a) Incoming raw materials, ingredients, and packaging components should be inspected upon receipt to ensure that they are suitable for processing. Raw materials should be received in an area separate from the processing areas. Prior to being placed in inventory, ingredients susceptible to microbiological contamination which would render them unsuitable for processing either should be examined for microbiological condition or should be received under a supplier's guarantee that they are of a microbiological condition suitable for use in processing low-acid foods. Products should be held prior to processing in such a manner as to minimize growth of microorganisms.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. Where the blanched food product is washed prior to filling, potable water should be used.

(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.

(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. This may be done by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(e) When normally low-acid fruits, vegetables, or vegetable products require sufficient acidification to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process.

§ 507.83 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors which may affect the scheduled process (e.g., minimum headspace, consistency, maximum drained weight, etc.), shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, where necessary, but not be limited to microbial thermal death time data, process calculations based on product heat penetration data, inoculated

packs, and incubation tests. Product heat penetration data may be mathematically converted in calculating processes for different container sizes and thermal processing temperatures. If incubation tests are necessary, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for establishing scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial production runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.

§ 507.87 Operations in the thermal processing room.

(a) Scheduled processes and venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or shall be made readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration.

(b) All retort baskets, trucks, cars, or crates containing unretorted food product, or some of the containers on the top of each basket, shall be plainly and conspicuously marked with a heat sensitive indicator, or by other effective means, which will visually indicate to thermal processing personnel whether or not each such unit has been retorted.

(c) The initial temperature of the contents of the containers to be processed shall be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process.

(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time specified in the scheduled process is achieved. Pocket or wrist watches shall not be considered satisfactory for timing purposes.

(e) For continuous agitating retorts, the condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. A record shall be kept to show how it is functioning.

§ 507.89 Deviations in processing.

Whenever any process is less than the scheduled process for any low-acid food or container system as disclosed from records, by processor check, or otherwise, the commercial processor of such low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, shall set aside that portion of the production involved for further evaluation as to any potential

public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless such evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside either shall be fully reprocessed to render it commercially sterile or it shall be destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commercial sterility or after the determination that no significant potential for public health hazard exists, that portion of the production involved may be shipped in normal distribution. Otherwise, the portion of the production involved shall be destroyed.

Subpart F—Records and Reports

§ 507.110 Processing and production records.

(a) Processing and production information shall be entered by the retort or processing system operator, or other designated person, on forms which shall include the product, the code number, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the minimum initial temperature, the actual processing time and temperature, the mercury-in-glass and recording thermometer readings, and other appropriate processing data. Closing machine vacuum (in vacuum-packed products), maximum drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

(1) *Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and/or temperature to which vented, (as applicable).

(2) *Agitating retorts.* Functioning of condensate bleeder; retort speed; and, where specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.

(3) *Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.

(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature indicating device and the temperature recorder; product temperature in the final heater outlet as indicated by the temperature recorder-controller; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-

product regenerator is used; product flow rate, as determined by the metering pump or by filling and closing rates; sterilization media flow rate and/or temperature; retention time of containers, and closures where applicable, in the sterilizing environment; and, where a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

(5) *Flame sterilizers.* Container conveyor speed; surface temperature at the end of the holding period; nature of container.

(b) Recording thermometer charts shall be identified by date, and other data as necessary, so they can be correlated with the written record of lots processed. Each entry on the record shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and the retort or processing system operator or such designated person shall sign or initial each record form. Not later than 1 working day after the actual process, and prior to shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed by the person conducting the review.

(c) Written records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and shall be reviewed by management with sufficient frequency to assure that the containers are hermetically sealed.

(d) Copies of all records provided for in this part except those required under § 507.83 establishing scheduled processes, shall be retained at the processing plant for a period of not less than 1 year, and at the processing plant or other reasonably accessible location for an additional 2 years. If during the first year of the 3-year record retention period the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.

PART 508—EMERGENCY PERMIT CONTROL

Subpart A—General Provisions

Sec.	
508.3	Definitions.
508.5	Determination of the need for a permit.
508.6	Revocation of determination of need for permit.
508.7	Issuance or denial of permit.
508.10	Suspension and reinstatement of permit.
508.12	Manufacturing, processing, or packing without a permit or in violation of a permit.

Sec. 508.19 Establishment of requirements for exemption from section 404 of the act.

Subpart B—Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit

508.35 Thermal processing of low-acid animal foods packaged in hermetically sealed containers.

AUTHORITY: Secs. 402, 404, 701, 52 Stat. 1046-1047 as amended, 1048, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 342, 344, 371.

Subpart A—General Provisions

§ 508.3 Definitions.

(a) The definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part.

(b) "Commissioner" means the Commissioner of Food and Drugs.

(c) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended.

(d) "Permit" means an emergency permit issued by the Commissioner pursuant to section 404 of the act for such temporary period of time as may be necessary to protect the public health.

(e) "Manufacture, processing, or packing of food in any locality" means activities conducted in a single plant or establishment, a series of plants under a single management, or all plants in an industry or region, by a manufacturer, processor, or packer.

§ 508.5 Determination of the need for a permit.

(a) Whenever the Commissioner determines after investigation that a manufacturer, processor, or packer of a food for which a regulation has been promulgated in Subpart B of this part does not meet the mandatory conditions and requirements established in such regulation, he shall issue to such manufacturer, processor, or packer an order determining that a permit shall be required before the food may be introduced or delivered for introduction into interstate commerce by that person. The order shall specify the mandatory conditions and requirements with which there is a lack of compliance.

(1) The manufacturer, processor, or packer shall have 3 working days after receipt of such order within which to file objections. Such objections may be filed by telegram, telex, or any other mode of written communication addressed to the Food and Drug Administration, Bureau of Foods, 200 C St. SW., Washington, DC 20204. If such objections are filed, the determination is stayed pending a hearing to be held within 5 working days after the filing of objections on the issues involved unless the Commissioner determines that the objections raise no genuine and substantial issue of fact to justify a hearing.

(2) If the Commissioner finds that there is an imminent hazard to health, the order shall contain this finding and the reasons therefor, and shall state that the determination of the need for a permit is effective immediately pending an expedited hearing.

(b) A hearing under this section shall be conducted by the Commissioner or his designee at a location agreed upon by the objector and the Commissioner or, if such agreement cannot be reached, at a location designated by the Commissioner. The manufacturer, processor, or packer shall have the right to cross-examine the Food and Drug Administration's witnesses and to present witnesses on his own behalf.

(c) Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner shall determine whether a permit is required and shall so inform the manufacturer, processor, or packer in writing, with the reasons for his decision.

(d) The Commissioner's determination of the need for a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay a determination of the need for a permit pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

§ 508.6 Revocation of determination of need for permit.

(a) A permit shall be required only during such temporary period as is necessary to protect the public health.

(b) Whenever the Commissioner has reason to believe that a permit holder is in compliance with the mandatory requirements and conditions established in Subpart B of this part and is likely to remain in compliance, he shall, on his own initiative or on the application of the permit holder, revoke both the determination of need for a permit and the permit that had been issued. If denied, the applicant shall, upon request, be afforded a hearing conducted in accordance with § 508.5 (b) and (c) as soon as practicable. Such revocation is without prejudice to the initiation of further permit proceedings with respect to the same manufacturer, processor, or packer should later information again show the need for a permit.

§ 508.7 Issuance or denial of permit.

(a) After a determination and notification by the Commissioner in accordance with the provisions of § 508.5 that a manufacturer, processor, or packer requires a permit, such manufacturer, processor, or packer may not thereafter introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by him unless he holds a permit issued by the Commissioner or obtains advance written approval of the Food and Drug Administration pursuant to § 508.12(a).

(b) Any manufacturer, processor, or packer for whom the Commissioner has made a determination that a permit is necessary may apply to the Commissioner for the issuance of such a permit. The application shall contain such data and information as is necessary to show that all mandatory requirements and conditions for the manufacture, processing or packing of a food for which regulations are established in Subpart B of

this part are met and, in particular, shall show that the deviations specified in the Commissioner's determination of the need for a permit have been corrected or suitable interim measures established. Within 10 working days after receipt of such application, (except that the Commissioner may extend such time an additional 10 working days where necessary), the Commissioner shall issue a permit, deny the permit, or offer the applicant a hearing conducted in accordance with § 508.5 (b) and (c) as to whether the permit should be issued. The Commissioner shall issue such a permit to which shall be attached, in addition to the mandatory requirements and conditions of Subpart B of this part, any additional requirements or conditions which may be necessary to protect the public health if he finds that all mandatory requirements and conditions of Subpart B of this part are met or suitable interim measures are established.

(c) Denial of a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay such denial pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

§ 508.10 Suspension and reinstatement of permit.

(a) Whenever the Commissioner finds that a permit holder is not in compliance with the mandatory requirements and conditions established by the permit, he shall immediately suspend the permit and so inform the permit holder, with the reasons for the suspension.

(b) Upon application for reinstatement of a permit, the Commissioner shall, within 10 working days, reinstate the permit if he finds that the person is in compliance with the mandatory requirements and conditions established by the permit or deny the application.

(c) Any person whose permit has been suspended or whose application for reinstatement has been denied may request a hearing. The hearing shall be conducted by the Commissioner or his designee within 5 working days of receipt of the request at a location agreed upon by the objector and the Commissioner or, if an agreement cannot be reached, at a location designated by the Commissioner. The permit holder shall have the right to present witnesses on his own behalf and to cross-examine the Food and Drug Administration's witnesses.

(d) Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner shall determine whether the permit shall be reinstated and shall so inform the permit holder, with the reasons for his decision.

(e) Denial of an application for reinstatement of a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay such denial pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

§ 508.12 Manufacturing, processing, or packing without a permit or in violation of a permit.

(a) A manufacturer, processor, or packer may continue at his own risk to manufacture, process, or pack without a permit a food for which the Commissioner has determined that a permit is required. All food so manufactured, processed, or packed during such period without a permit shall be retained by the manufacturer, processor, or packer and may not be introduced or delivered for introduction into interstate commerce without the advance written approval of the Food and Drug Administration. Such approval may be granted only upon an adequate showing that such food is free from microorganisms of public health significance. The manufacturer, processor, or packer may provide to the Commissioner, for his consideration in making any such determination, an evaluation of the potential public health significance of such food by a competent authority in accordance with procedures recognized as being adequate to detect any potential hazard to public health. Within 20 working days after receipt of a written request for such written approval the Food and Drug Administration shall either issue such written approval or deny the request. If the request is denied, the applicant shall, upon request, be afforded a prompt hearing conducted in accordance with § 508.5 (b) and (c).

(b) Except as provided in paragraph (a) of this section, no manufacturer, processor, or packer may introduce or deliver for introduction into interstate commerce without a permit or in violation of a permit a food for which the Commissioner has determined that a permit is required. Where a manufacturer, processor, or packer utilizes a consolidation warehouse or other storage facility under his control, interstate shipment of any such food from the point of production to that warehouse or storage facility shall not violate this paragraph, provided that no further introduction or delivery for introduction into interstate commerce is made from that consolidated warehouse or storage facility except as provided in paragraph (a) of this section.

§ 508.19 Establishment of requirements for exemption from section 404 of the act.

(a) Whenever the Commissioner finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he shall promulgate regulations in Subpart B of this part establishing requirements and conditions governing the manufacture, processing, or packing of the food necessary to protect the public health. Such regulations may be

proposed by the Commissioner on his own initiative or in response to a petition from any interested person. Petitions requesting promulgation of regulations in Subpart B of this part shall be in the form specified in § 2.65 of this chapter.

(b) A manufacturer, processor, or packer of a food for which a regulation has been promulgated in Subpart B of this part shall be exempt from the requirement for a permit only if he meets all of the mandatory requirements and conditions established in that regulation.

Subpart B—Requirements and Conditions for Exemption From or Compliance With an Emergency Permit

§ 508.35 Thermal processing of low-acid foods packaged in hermetically sealed containers.

(a) Inadequate or improper manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers may result in the distribution in interstate commerce of processed foods that may be injurious to health. The harmful nature of such foods cannot be adequately determined after these foods have entered into interstate commerce. The Commissioner of Food and Drugs therefore finds that, in order to protect the public health, it may be necessary to require any commercial processor, in any establishment engaged in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers, to obtain and hold a temporary emergency permit provided for under section 404 of the Federal Food, Drug, and Cosmetic Act. Such a permit may be required whenever the Commissioner finds, after investigation, that the commercial processor has failed to fulfill all the requirements of this section, including registration and the filing of process information, and the mandatory portions of Part 507 of this chapter. These requirements are intended to ensure safe manufacture, processing, and packing procedures and to permit the Food and Drug Administration to verify that these procedures are being followed. Such failure shall constitute a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the act to that establishment, pursuant to the procedures established in Subpart A of this part.

(b) The definitions in § 507.3 of this chapter are applicable when such terms are used in this section.

(c) Registration and process filing:
(1) *Registration.* A commercial processor when first engaging in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers in any state, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register with the Food and Drug Administration on Form FD-2541 (food canning establishment registration) information including (but not limited to) his name, principal place of business, the location of each establishment in which such processing is carried on,

the processing method in terms of the type of processing equipment employed, and a list of the low-acid foods so processed in each such establishment. These forms are available from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch, HFF-326, 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form shall be submitted to the Food and Drug Administration, Bureau of Foods, Division of Food Technology, HFF-419, 200 C St. SW., Washington, DC 20204. Commercial processors presently so engaged shall register not later than July 13, 1973. Commercial processors duly registered in accordance with this section shall notify the Food and Drug Administration not later than 90 days after such commercial processor ceases or discontinues the manufacture, processing, or packing of thermally processed foods in any establishment: *Provided*, That such notification shall not be required as to the temporary cessation necessitated by the seasonal character of the particular establishment's production or caused by temporary conditions including but not limited to strikes, lockouts, fire, or acts of God.

(2) *Process filing.* A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall, not later than 60 days after registration and prior to the packing of a new product, provide the Food and Drug Administration information as to the scheduled processes including but not limited to the processing method, type of retort or other thermal processing equipment employed, minimum initial temperatures, times and temperatures of processing, sterilizing value (F_0), or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process, for each such low-acid food in each container size: *Provided*, That the filing of such information does not constitute approval of the information by the Food and Drug Administration, and that information concerning processes and other data so filed shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905. This information shall be submitted on the following forms as appropriate: Form FD-2541a (food canning establishment and process filing for still retort processes), form FD-2541b (food canning establishment and process filing for agitating processes), or form FD-2541c (food canning establishment and process filing for other than still retort and agitating processes). These forms are available from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch, HFF-326, 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form(s) shall be submitted to the Food and Drug Administration, Bureau of Foods, Division of Food Technology, HFF-419, 200 C St. SW., Washington, DC 20204.

(i) If all the necessary information is not available for existing products, the

processor shall, at the time the existing information is provided to the Food and Drug Administration request in writing an extension of time for submission of such information, specifying what additional information is to be supplied and the date by which it is to be submitted. Within 30 working days after receipt of such request the Food and Drug Administration shall either grant or deny such request in writing.

(ii) If a packer intentionally makes a change in a previously filed scheduled process by reducing the initial temperature or retort temperature, reducing the time of processing, or changing the product formulation, the container, or any other condition basic to the adequacy of scheduled process, he shall prior to using such changed process obtain substantiation by qualified scientific authority as to its adequacy. Such substantiation may be obtained by telephone, telegram, or other media, but must be promptly recorded, verified in writing by the authority, and contained in the packer's files for review by the Food and Drug Administration. Within 30 days after first use, the packer shall submit to the Food and Drug Administration, Bureau of Foods, 200 C St. SW., HFF-419, Washington, DC 20204 a complete description of the modifications made and utilized, together with a copy of his file record showing prior substantiation by a qualified scientific authority as to the safety of the changed process. Any intentional change of a previously filed scheduled process or modification thereof in which the change consists solely of a higher initial temperature, a higher retort temperature, or a longer processing time, shall not be considered a change subject to this paragraph, but if thereafter that modification is to be regularly scheduled, the modified process shall be promptly filed as a scheduled process, accompanied by full information on the specified forms as provided in this paragraph.

(iii) Many packers employ an "operating" process in which retort operators are instructed to use retort temperatures and/or processing times slightly in excess of those specified in the scheduled process as a safety factor to compensate for minor fluctuations in temperature or time to assure that the minimum times and temperatures in the scheduled process are always met. This would not constitute a modification of the scheduled process.

(3) *Process adherence and information.* (i) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers in any registered establishment shall process each low-acid food in each container size in conformity with at least the scheduled processes and modifications filed pursuant to paragraph (c) (2) of this section.

(ii) *Process information availability.* When requested by the Food and Drug Administration in writing, a commercial processor engaged in thermal processing of low-acid foods packaged in hermetically sealed containers shall provide the Food and Drug Administration with any information concerning processes and

procedures which is deemed necessary by the Food and Drug Administration to determine the adequacy of the process: *Provided*, That the furnishing of such information does not constitute approval of the information by the Food and Drug Administration, and that the information concerning processes and other data so furnished shall be regarded as trade secrets within the meaning of 21 U.S.C. 331 (j) and 18 U.S.C. 1905.

(d) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall promptly report to the Food and Drug Administration any instance of spoilage or process deviation the nature of which indicates potential health significance where any lot of such food has in whole or in part entered distribution.

(e) A commercial processor engaged in thermal processing of low-acid foods packaged in hermetically sealed containers shall promptly report to the Food and Drug Administration any instance wherein any lot of such food, which may be injurious to health by reason of contamination with microorganisms, has in whole or in part entered distribution.

(f) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall have prepared and in his files a current procedure which he will use for products under his control and which he will ask his distributor to follow, including plans for effecting recalls of any product that may be injurious to health; for identifying, collecting, warehousing, and controlling the product; for determining the effectiveness of such recall; for notifying the Food and Drug Administration of any such recall; and for implementing such recall program.

(g) All operators of retorts, thermal processing systems, aseptic processing and packaging systems, or other thermal processing systems, and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, aseptic processing and packaging systems operations or other thermal processing systems operations, and container closure inspections, and has satisfactorily completed the prescribed course of instruction: *Provided*, That this requirement shall not apply in the State of California as listed in paragraph (j) of this section and shall not apply until March 25, 1975 in any other State. The Commissioner will not withhold approval of any school qualified to give such instruction.

(h) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall prepare, review, and retain at the processing plant for a period of not less than 1 year, and at the processing plant or other reasonably accessible location for an additional 2 years, all records of processing, deviations in processing, container closure inspections, and other records specified in Part 507 of this chapter. If during the first year of the 3-year record retention period the processing plant is closed for

a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack. Upon written demand during the course of a factory inspection pursuant to section 704 of the act by a duly authorized employee of the Food and Drug Administration, a commercial processor shall permit the inspection and copying by such employee of these records to verify the adequacy of processing, the integrity of container closures, and the coding of the products.

(i) This section shall not apply to the commercial processing of any food processed under the continuous inspection of the meat and poultry inspection program of the Animal and Plant Health Inspection Service of the Department of Agriculture under the Federal Meat Inspection Act (34 Stat. 1256, as amended by 81 Stat. 584 (21 U.S.C. 601 et seq.)) and the Poultry Products Inspection Act (71 Stat. 441, as amended by 82 Stat. 791; 21 U.S.C. 451 et seq.).

(j) Compliance with State regulations: (1) Wherever the Commissioner finds that any State regulates the commercial thermal processing of low-acid foods in accordance with effective regulations specifying at least the requirements of Part 507 of this chapter, he shall issue a notice stating that compliance with such State regulations shall constitute compliance with Part 507 of this chapter. However, the provisions of this section shall remain applicable to the commercial processing of low-acid foods in any such State, except that, either the State through its regulatory agency or each processor of low-acid foods in such State shall file with the Bureau of Foods the registration information and the processing information prescribed in paragraph (c) of this section.

(2) The Commissioner finds that the regulations adopted by the State of California under the laws relating to cannery inspections governing thermal processing of low-acid foods packaged in hermetically sealed containers satisfy the requirements of Part 507 of this chapter.

Accordingly, processors, who under the laws relating to cannery inspections are licensed by the State of California and who comply with such state regulations, shall be deemed to comply with the requirements of Part 507 of this chapter.

(k) Imports: (1) This section shall apply to any foreign commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers and offering such foods for import into the United States except that, in lieu of providing for the issuance of an emergency permit under paragraph (a) of this section, the Commissioner will request the Secretary of the Treasury to refuse admission into the United States, pursuant to section 801 of the act, of any such low-acid foods which the Commissioner determines, after investigation, may result in the distribution in interstate commerce of processed foods that may be injurious to health as set forth in paragraph (a) of this section.

(2) Any such food refused admission shall not be admitted until such time as

the Commissioner may determine that the commercial processor offering the food for import is in compliance with the requirements and conditions of this section and that such food is not injurious to health. For the purpose of making such determination, the Commissioner reserves the right for a duly authorized employee of the Food and Drug Administration to inspect the commercial processor's manufacturing, processing, and packing facilities.

(l) The following data and information submitted to the Food and Drug Administration pursuant to this section are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter:

(1) Manufacturing methods or processes, including quality control information.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

PART 509—UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL

Subpart A—General Provisions

- Sec.
509.3 Definitions and interpretations.
509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

- 509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

AUTHORITY: Secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1785-1788 as amended; 21 U.S.C. 342(a), 346, 348, 371.

Subpart A—General Provisions

§ 509.3 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in this part.

(b) Unavoidable natural, environmental, or industrial contaminants include any poisonous or deleterious substance added to any food where such substance cannot be avoided by good manufacturing practice.

§ 509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor

(France); Colphen (Germany); and Kanacior (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk and eggs). Investigations by the Food and Drug Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food-packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packaging materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment, any other PCB-containing equipment, machinery and materials

wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (a) its toxicity; (b) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (c) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (d) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufactured dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 part per million in eggs.

(5) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(6) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) [Reserved]

(9) 10 parts per million in paper food-packaging material intended for or used with finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20852.

NOTE: At 38 FR 22794, Aug. 24, 1973, the following appeared concerning § 509.30(a) (9):

*** § 509.30(a) (9) is hereby stayed pending full review of the objections and requests for hearing. ***

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by § 509.30(a) (9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973 containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

PART 564—DEFINITIONS AND STANDARDS FOR ANIMAL FOOD

Subpart A—General Provisions

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| Sec. | |
| 564.3 | Definitions and interpretations. |
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| 564.12 | General methods for water capacity and fill of container. |
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| 564.17 | Temporary permits for interstate shipment of experimental packs of animal food varying from the requirements of definitions and standards of identity. |

Subpart B—Food Additives in Standardized Animal Food

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| 564.20 | Food additives proposed for use in animal foods for which definitions and standards of identity are established. |
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AUTHORITY: The provisions of this Part 10 issued under secs. 401, 701, 52 Stat. 1046, 1055 as amended; 21 U.S.C. 341, 371.

§ 564.3 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in regulations promulgated under the act.

(b) If a regulation prescribing a definition and standard of identity for a food has been promulgated under section 401 of the act and the name therein specified for the food is used in any other regulation under section 401 or any other provision of the act, such name means the food which conforms to such definition and standard, except as otherwise specifically provided in such other regulation.

(c) No provision of any regulation prescribing a definition and standard of identity or standard of quality or fill of container under section 401 of the act shall be construed as in any way affecting the concurrent applicability of the general provisions of the act and the regulations thereunder relating to adulteration and misbranding. For example, all regulations under section 401 of the act contemplate that the food and all articles used as components or ingredients thereof shall not be poisonous or deleterious and shall be clean, sound, and fit for food. A provision in such regulations for the use of coloring or flavoring does not authorize such use under circumstances or in a manner whereby damage or inferiority is concealed or whereby the food is made to appear better or of greater value than it is.

(d) "Safe and suitable" means that the ingredient:

(1) Performs an appropriate function in the food in which it is used.

(2) Is used at a level no higher than necessary to achieve its intended purpose in that food.

(3) Is not a food additive or color additive as defined in section 201 (s) or (t) of the act as used in that food, or is a food additive or color additive as so defined and is used in conformity with regulations established pursuant to section 409 or 706 of the act.

§ 564.5 Procedure for establishing food standards under the Federal Food, Drug, and Cosmetic Act.

Section 401 of the Federal Food, Drug, and Cosmetic Act provides for the formulation of definitions and standards of identity and standards of quality and fill of container for foods. This procedure is condensed as follows:

(a) If the petitioner shows that he is an interested person and furnishes reasonable grounds for his proposal, it is the duty of the Commissioner to publish the proposal and afford opportunity for other interested persons to comment on it. After a study of all the facts available and of the comments received, the Commissioner will act upon the proposal and publish an order, to which objection may be taken by persons who would be adversely affected. Thus the issues in controversy are singled out for a public hearing.

(b) Practical administration of the law requires that there be a substantial showing of merit before any proposal is published. In passing on proposals submitted by petitioners for initiating actions, it will be the policy of the Food and Drug Administration to consider that reasonable grounds have been furnished when:

(1) The proposal includes or is accompanied by a statement of the facts that the petitioner asserts he is in a position to substantiate by evidence in the event the proceedings lead to a public hearing.

(2) The facts declared furnish substantial support of the proposal and warrant a conclusion that the proposal is reasonable.

(3) The proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Opportunity will be given to amend petitions regarded as inadequate.

(d) At any time prior to the issuance of an order acting on his proposal under section 701(e)(1) of the act, the petitioner may withdraw his petition without prejudice to a future filing. Notice of withdrawal of the petition and termination of the rulemaking proceeding will be published in the FEDERAL REGISTER.

§ 564.6 Review of Codex Alimentarius Food Standards.

(a) All food standards adopted by the Codex Alimentarius Commission will be reviewed by the Food and Drug Administration and will be accepted without change, accepted with change, or not accepted.

(b) Review of Codex standards will be accomplished in one of the following three ways:

(1) Any interested person may petition the Commissioner to adopt a Codex standard, with or without change, by proposing a new standard or an appropriate amendment of an existing standard, pursuant to section 401 of the act. Any such petition shall specify any deviations from the Codex standard, and the reasons for any such deviations. The Commissioner shall publish such a petition in the FEDERAL REGISTER as a proposal, with an opportunity for comment, if reasonable grounds are provided in the petition. Any published proposal shall state any deviations from the Codex standard and the stated reasons therefor.

(2) The Commissioner may on his own initiative propose by publication in the FEDERAL REGISTER the adoption of a Codex standard, with or without change, through a new standard or an appropriate amendment to an existing standard, pursuant to section 401 of the act. Any such proposal shall specify any deviations from the Codex standard, and the reasons for any such deviations.

(3) Any Codex standard not handled under paragraph (b) (1) or (2) of this section may be published in the FEDERAL REGISTER for review and informal comment. Interested persons shall be requested to comment on the

desirability and need for the standard, on the specific provisions of the standard, on additional or different provisions that should be included in the standard, and on any other pertinent points. After reviewing all such comments, the Commissioner either shall publish a proposal to establish a food standard pursuant to section 401 of the act covering the food involved, or shall publish a notice terminating consideration of such a standard.

(c) All interested persons are encouraged to confer with different interest groups (consumers, industry, the academic community, professional organizations, and others) in formulating petitions or comments pursuant to paragraph (b) of this section. All such petitions or comments are requested to include a statement of any meetings and discussions that have been held with other interest groups. Appropriate weight will be given by the Commissioner to petitions or comments that reflect a consensus of different interest groups.

§ 564.8 Conformity to definitions and standards of identity.

In the following conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard, unless such ingredient is an incidental additive introduced at a nonfunctional and insignificant level as a result of its deliberate and purposeful addition to another ingredient permitted by the terms of the applicable standard and the presence of such incidental additive in unstandardized foods has been exempted from label declaration as provided in § 501.100 of this chapter.

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

§ 564.12 General methods for water capacity and fill of container.

For the purposes of regulations promulgated under section 401 of the act:

(a) The term "general method for water capacity of containers" means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Wash, dry, and weigh the empty container.

(3) Fill the container with distilled water at 68° F to 3/16 inch vertical distance below the top level of the container, and weigh the container thus filled.

(4) Subtract the weight found in paragraph (a) (2) of this section from the weight found in paragraph (a) (3) of this section. The difference shall be considered to be the weight of water required to fill the container.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in paragraph (a) (2) to (4) of this section, except that under paragraph (a) (3) of this section, fill the container to the level of the top thereof.

(b) The term "general method for fill of containers" means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Measure the vertical distance from the top level of the container to the top level of the food.

(3) Remove the food from the container; wash, dry, and weigh the container.

(4) Fill the container with water to $\frac{3}{16}$ inch vertical distance below the top level of the container. Record the temperature of the water, weigh the container thus filled, and determine the weight of the water by subtracting the weight of the container found in paragraph (b) (3) of this section.

(5) Maintaining the water at the temperature recorded in paragraph (b) (4) of this section, draw off water from the container as filled in paragraph (b) (4) of this section to the level of the food found in paragraph (b) (2) of this section, weigh the container with remaining water, and determine the weight of the remaining water by subtracting the weight of the container found in paragraph (b) (3) of this section.

(6) Divide the weight of water found in paragraph (b) (5) of this section by the weight of water found in paragraph (b) (4) of this section, and multiply by 100. The result shall be considered to be the percent of the total capacity of the container occupied by the food.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in paragraph (b) (2) to (6) of this section, except that under paragraph (b) (4) of this section, fill the container to the level of the top thereof.

§ 564.14 General statements of substandard quality and substandard fill of container.

For the purposes of regulations promulgated under section 401 of the act:

(a) The term "general statement of substandard quality" means the statement "Below Standard in Quality Good Food—Not High Grade" printed in two lines of Cheltenham bold condensed caps. The words "Below Standard in Quality" constitute the first line, and the second immediately follows. If the quantity of the contents of the container is less than 1 pound, the type of the first line is 12-point and of the second, 8-point. If such quantity is 1 pound or more, the type of the first line is 14-point, and of the second, 10-point. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle. Such statement, with enclosing lines, is on a strongly contrasting, uniform back-

ground, and is so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

(b) The term "general statement of substandard fill" means the statement "Below Standard in Fill" printed in Cheltenham bold condensed caps. If the quantity of the contents of the container is less than 1 pound, the statement is in 12-point type; if such quantity is 1 pound or more, the statement is in 14-point type. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle; but if the statement specified in paragraph (a) of this section is also used, both statements (one following the other) may be enclosed within the same rectangle. Such statement or statements, with enclosing lines, are on a strongly contrasting, uniform background, and are so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

§ 564.17 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

(a) The Food and Drug Administration recognizes that before petitions to amend food standards can be submitted, appropriate investigations of potential advances in food technology sometimes require tests in interstate markets of the advantages to and acceptance by consumers of experimental packs of food varying from applicable definitions and standards of identity prescribed under section 401 of the act.

(b) It is the purpose of the Administration to permit such tests when it can be ascertained that the sole purpose of the tests is to obtain data necessary for reasonable grounds in support of a petition to amend food standards, that the tests are necessary to the completion or conclusiveness of an otherwise adequate investigation, and that the interests of consumers are adequately safeguarded; permits for such tests shall normally be for a period not to exceed 15 months. The Commissioner, for good cause shown by the applicant, may provide for a longer test market period. The Administration will therefore refrain from recommending regulatory proceedings under the act on the charge that a food does not conform to an applicable standard, if the person who introduces or causes the introduction of the food into interstate commerce holds an effective permit from the Commissioner providing specifically for those variations in respect to which the food fails to conform to the applicable definition and standard of identity. The test period will begin on the date the person holding an effective permit from the Commissioner introduces or causes the introduction of the food covered by the permit into interstate com-

merce but no later than 3 months after notice of the issuance of the permit is published in the FEDERAL REGISTER. The Commissioner shall be notified in writing of the date on which the test period begins as soon as it is determined.

(c) Any person desiring a permit may file with the Commissioner a written application in triplicate containing as part thereof the following:

(1) Name and address of the applicant.

(2) A statement of whether or not the applicant is regularly engaged in producing the food involved.

(3) A reference to the applicable definition and standard of identity (citing applicable section of regulations).

(4) A full description of the proposed variation from the standard.

(5) The basis upon which the food so varying is believed to be wholesome and nondeleterious.

(6) The amount of any new ingredient to be added; the amount of any ingredient, required by the standard, to be eliminated; any change of concentration not contemplated by the standard; or any change in name that would more appropriately describe the new product under test. If such new ingredient is not a commonly known food ingredient, a description of its properties and basis for concluding that it is not a deleterious substance.

(7) The purpose of effecting the variation.

(8) A statement of how the variation is of potential advantage to consumers. The statement shall include the reasons why the applicant does not consider the data obtained in any prior investigations which may have been conducted sufficient to support a petition to amend the standard.

(9) The proposed label (or an accurate draft) to be used on the food to be marketed tested. The label shall conform in all respects to the general requirements of the act and shall provide a means whereby the consumer can distinguish between the food being tested and such food complying with the standard.

(10) The period during which the applicant desires to introduce such food into interstate commerce, with a statement of the reasons supporting the need for such period. If a period longer than 15 months is requested, a detailed explanation of why a 15-month period is inadequate shall be provided.

(11) The probable amount of such food that will be distributed. The amount distributed should be limited to the smallest number of units reasonably required for a bona fide market test. Justification for the amount requested shall be included.

(12) The areas of distribution.

(13) The address at which such food will be manufactured.

(14) A statement of whether or not such food has been or is to be distributed in the State in which it was manufactured.

(15) If it has not been or is not to be so distributed, a statement showing why.

(16) If it has been or is to be so distributed, a statement of why it is deemed

necessary to distribute such food in other States.

(d) The Commissioner may require the applicant to furnish samples of the food varying from the standard and to furnish such additional information as may be deemed necessary for action on the application.

(e) If the Commissioner concludes that the variation may be advantageous to consumers and will not result in failure of the food to conform to any provision of the act except section 403(g), a permit shall be issued to the applicant for interstate shipment of such food. The terms and conditions of the permit shall be those set forth in the application with such modifications, restrictions, or qualifications as the Commissioner may deem necessary and state in the permit.

(f) The terms and conditions of the permit may be modified at the discretion of the Commissioner or upon application of the permittee during the effective period of the permit.

(g) The Commissioner may revoke a permit for cause, which shall include but not be limited to the following:

(1) That the permittee has introduced a food into interstate commerce contrary to the terms and conditions of the permit.

(2) That the application for a permit contains an untrue statement of a material fact.

(3) That the need therefor no longer exists.

(h) During the period within which any permit is effective, it shall be deemed to be included within the terms of any guaranty or undertaking otherwise effective pursuant to the provisions of section 303(c) of the act.

(i) If an application is made for an extension of the permit, it shall be accompanied by a description of experiments conducted under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered necessary. The application for an extension shall be filed not later than 3 months prior to the expiration date of the permit and shall be accompanied by a petition to amend the affected food standard. If the Commissioner concludes that it will be in the interest of consumers to issue an extension of the time period for the market test, a notice will be published in the FEDERAL REGISTER stating that fact. The notice will include an invitation to all interested persons to participate in the market test under the same conditions that applied to the initial permit holder, including labeling and the amount to be distributed, except that the designated area of distribution shall not apply. The extended market test period shall not begin prior to the publication of a notice in the FEDERAL REGISTER granting the extension and shall terminate either on the effective date of an affirmative order ruling on the proposal or 30 days after a negative order ruling on the proposal, whichever the case may be. Any interested person who accepts the invitation to participate in the extended market

test shall notify the Commissioner in writing of that fact, the amount to be distributed, and the area of distribution; and along with such notification, he shall submit the labeling under which the food is to be distributed.

(j) Notice of the granting or revocation of any permit shall be published in the FEDERAL REGISTER.

(k) All applications for a temporary permit, applications for an extension of a temporary permit, and related records are available for public disclosure when the notice of a permit or extension thereof is published in the FEDERAL REGISTER. Such disclosure shall be in accordance with the rules established in Part 4 of this chapter.

Subpart B—Food Additives in Standardized Animal Food

§ 564.20 Food additives proposed for use in animal foods for which definitions and standards of identity are established.

(a) Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in this subchapter E shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the act requires that the Commissioner publish notice of a petition for the establishment of a food-additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food-additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food-additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this subchapter E.

PART 570—FOOD ADDITIVES

Subpart A—General Provisions

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AUTHORITY: Secs. 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 570.3 Definitions.

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

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

(c) "Commissioner" means the Commissioner of Food and Drugs.

(d) As used in this part, the term "act" means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936 (52 Stat. 1040 et seq., as amended; 21 U.S.C. 301-392).

(e) "Food additives" includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. "Affecting the characteristics of food" does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(f) "Common use in food" refers to consumption of a substance by animals, regardless of the number of manufacturers who may produce it.

(g) The word "substance" in the definition of the term "food additive" includes a food or feed or a component of a food or feed consisting of one or more ingredients.

(h) "Scientific procedures" include not only original animal, analytical, and other scientific studies, but also an unprejudiced compilation of reliable information, both favorable and unfavorable, drawn from the scientific literature.

(i) "Safe" means that after reviewing all available evidence, including:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use;

(2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(3) Safety factors which in the opinion of experts qualified by scientific

training and experience to evaluate the safety of food and feed and food and feed ingredients are generally recognized as appropriate in the use of animal experimentation data; the Food and Drug Administration can conclude that no significant risk of harm will result when the substance is used as intended.

(j) The term "nonperishable processed food" means any processed food not subject to rapid decay or deterioration that would render it unfit for consumption. Not included are hermetically sealed foods and other processed foods requiring refrigeration.

(k) "Generally recognized as safe" means general recognition of safety by experts qualified by scientific training and experience to evaluate the safety of such a substance, as determined through the procedure prescribed by § 570.30 (b)(2). On the basis of scientific data derived from published literature, available to experts generally, reporting on credible toxicological testing, or for those substances used in food prior to January 1, 1958, on the basis of a reasoned judgment founded in experience with common food use, the substance is recognized to have no significant risk of harm if used as intended, taking into account in either case:

- (1) Reasonably anticipated patterns of consumption of the substance and of any substance formed in or on food because of the use of the substance;
- (2) The cumulative effect of the substance, and any chemically or pharmacologically related substance, in the diet of man or animals; and
- (3) Safety factors appropriate for the utilization of animal experimentation data.

§ 570.6 Opinion letters on food additive status.

(a) Over the years the Food and Drug Administration has given informal written opinions to inquirers as to the safety of articles intended for use as components of, or in contact with, food. Prior to the enactment of the Food Additives Amendment of 1958 (Public Law 85-929, Sept. 6, 1958), these opinions were given pursuant to section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, which reads in part: "A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health;"

(b) Since enactment of the Food Additives Amendment, the Food and Drug Administration has advised such inquirers that an article:

- (1) Is a food additive within the meaning of section 201(s) of the act; or
- (2) Is generally recognized as safe (GRAS); or
- (3) Has prior sanction or approval under that amendment; or
- (4) Is not a food additive under the conditions of intended use.

(c) In the interest of the public health, such articles which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1), or to be generally

recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be re-examined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.

(d) Because of the time span involved, copies of many of the letters in which the Food and Drug Administration has expressed an informal opinion concerning the status of such articles may no longer be in the file of the Food and Drug Administration. In the absence of information concerning the names and uses made of all the articles referred to in such letters, their safety of use cannot be reexamined. For this reason all food additive status opinions of the kind described in paragraph (c) of this section given by the Food and Drug Administration are hereby revoked.

(e) The prior opinions of the kind described in paragraph (c) of this section will be replaced by qualified and current opinions if the recipient of each such letter forwards a copy of each to the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Veterinary Medicine, Office of Compliance (HFV-200), 5600 Fishers Lane, Rockville, MD 20852, along with a copy of his letter of inquiry, on or before July 23, 1970.

(f) This section does not apply to food additive status opinion letters pertaining to articles that were considered by the Food and Drug Administration to be food additives nor to articles included in regulations in this subchapter E if the articles are used in accordance with the requirements of such regulations.

(Sec. 201, 72 Stat. 1784-88, as amended; 21 U.S.C. 321)

§ 570.15 Adoption of regulation on initiative of Commissioner.

(a) The Commissioner upon his own initiative may propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used. Notice of such proposal shall be published in the FEDERAL REGISTER and shall state the reasons for the proposal.

(b) Action upon a proposal made by the Commissioner shall, after publication of the notice, proceed as provided in §§ 571.1 and 571.100 and section 409 of the act.

§ 570.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

A food additive or food containing a food additive intended for investigational use by qualified experts shall be exempt from the requirements of section 409 of the act under the following conditions:

(a) If intended for investigational use in vitro or in laboratory research animals, it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for investigational use only in laboratory re-

search animals or for tests in vitro. Not for use in humans.

(b) If intended for use in animals other than laboratory research animals and if the edible products of the animals are to be marketed as food, permission for the marketing of the edible products as food has been requested by the sponsor, and authorization has been granted by the Food and Drug Administration in accordance with § 511.1 of this chapter or by the Department of Agriculture in accordance with 9 CFR 309.17, and it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for use only in investigational animals. Not for use in humans.

Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

§ 570.18 Tolerances for related food additives.

(a) Food additives that cause similar or related pharmacological effects will be regarded as a class, and in the absence of evidence to the contrary, as having additive toxic effects and will be considered as related food additives.

(b) Tolerances established for such related food additives may limit the amount of a common component that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present or may limit the total amount of related food additives that may be present.

(c) Where food additives from two or more chemicals in the same class are present in or on a food, the tolerance for the total of such additives shall be the same as that for the additive having the lowest numerical tolerance in this class, unless there are available methods that permit quantitative determination of the amount of each food additive present or unless it is shown that a higher tolerance is reasonably required for the combined additives to accomplish the physical or technical effect for which such combined additives are intended and that the higher tolerance will be safe.

(d) Where residues from two or more additives in the same class are present in or on a food and there are available methods that permit quantitative determination of each residue, the quantity of combined residues that are within the tolerance may be determined as follows:

- (1) Determine the quantity of each residue present.
- (2) Divide the quantity of each residue by the tolerance that would apply if it occurred alone, and multiply by 100 to determine the percentage of the permitted amount of residue present.
- (3) Add the percentages so obtained for all residues present.
- (4) The sum of the percentages shall not exceed 100 percent.

§ 570.19 Pesticide chemicals in processed foods.

When pesticide chemical residues occur in processed foods due to the use of

raw agricultural commodities that bore or contained a pesticide chemical in conformity with an exemption granted or a tolerance prescribed under section 408 of the act, the processed food will not be regarded as adulterated so long as good manufacturing practice has been followed in removing any residue from the raw agricultural commodity in the processing (such as by peeling or washing) and so long as the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. But when the concentration of residue in the processed food when ready to eat is higher than the tolerance prescribed for the raw agricultural commodity, the processed food is adulterated unless the higher concentration is permitted by a tolerance obtained under section 409 of the act. For example, if fruit bearing a residue of 7 parts per million of DDT permitted on the raw agricultural commodity is dried and a residue in excess of 7 parts per million of DDT results on the dried fruit, the dehydrated fruit is adulterated unless the higher tolerance for DDT is authorized by the regulations in this part. Food that is itself ready to eat, and which contains a higher residue than allowed for the raw agricultural commodity, may not be legalized by blending or mixing with other foods to reduce the residue in the mixed food below the tolerance prescribed for the raw agricultural commodity.

Subpart B—Food Additive Safety

§ 570.20 General principles for evaluating the safety of food additives.

(a) In reaching a decision on any petition filed under section 409 of the act, the Commissioner will give full consideration to the specific biological properties of the compound and the adequacy of the methods employed to demonstrate safety for the proposed use, and the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council. A petition will not be denied, however, by reason of the petitioner's having followed procedures other than those outlined in the publications of the National Academy of Sciences-National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedures. In reaching a decision, the Commissioner will give due weight to the anticipated levels and patterns of consumption of the additive specified or reasonably inferable. For the purposes of this section, the principles for evaluating safety of additives set forth in the above-mentioned publications will apply to any substance that may properly be classified as a food additive as defined in section 201(s) of the act.

(b) Upon written request describing the proposed use of an additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a food additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 570.22 Safety factors to be considered.

In accordance with section 409(c) (5) (C) of the act, the following safety factors will be applied in determining whether the proposed use of a food additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals.

§ 570.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) To provide assurance that any substance is absolutely safe for human or animal consumption is impossible.

(b) A substance used as food, or the intended use of which results or may reasonably be expected to result directly or indirectly in its becoming a component of food or affecting the characteristics of food, may be eligible for classification as generally recognized as safe (GRAS) under the following criteria:

(1) Substances that will be considered as GRAS and for which a promulgation in the FEDERAL REGISTER is not required:

(i) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without detrimental effect when used under reasonably anticipated patterns of consumption.

(ii) Substances defined in paragraph (b) (1) (i) of this section that have been modified by conventional processing as practiced prior to January 1, 1958.

(2) Substances that will be affirmed as GRAS by the Commissioner after he has given notice in the FEDERAL REGISTER that the status of such substance (and limitations, if any) is under consideration, invited experts qualified by scientific training and experience to evaluate the safety of foods and food ingredients to submit comments, reviewed all available evidence and the comments received, and found convincing evidence of its general recognition of safety:

(i) Substances defined in paragraph (b) (1) (i) of this section that have been modified by processes proposed for introduction into commercial use after January 1, 1958, where such processes may reasonably be expected to significantly alter the composition of the substance.

(ii) Substances that have had significant alteration of composition by breeding or selection and the change may reasonably be expected to alter to a significant

degree the nutritive value or the concentration of toxic constituents therein.

(iii) Distillates, isolates, extracts, concentrates of extracts, or reaction products of substances considered as GRAS.

(iv) Substances not of natural biological origin including those for which evidence is offered that they are identical with a GRAS counterpart of natural biological origin.

(v) Substances of natural biological origin intended for consumption for other than their nutrient properties.

(c) Substances that do not meet the criteria of paragraph (b) of this section are not eligible for GRAS status and hence require a food additive regulation promulgated under section 409 of the act, and no substance will be eligible for GRAS status if it has no history of food use or requires prescribed limitations for safe use.

(d) Any substance used in food must be of food-grade quality. The Commissioner regards the applicable specifications in the current edition of "Food Chemicals Codex" as establishing food grade unless he has by FEDERAL REGISTER promulgation established other specifications.

(e) If the Commissioner has not affirmed a given substance as GRAS on his own initiative, such affirmative ruling may be sought by submitting to the Commissioner a request containing all relevant usage and safety data.

(f) Substances listed as GRAS may require reclassification either because of the criteria established by this section or because of new information regarding safety. The initial results of a new investigation, even if not convincing with respect to potential harm, may establish that the substance in question can no longer be considered as GRAS. Newly reported information will be carefully evaluated by the Commissioner, along with other available information, to determine whether or not there has been a significant increase in risk to the public health from using the substance as intended. No change will be made in existing GRAS status until the Commissioner determines that the substance requires evaluation.

(g) If a responsible and substantial question of safety has been raised regarding a substance previously listed as GRAS, but the main weight of the scientific evidence still establishes safety within certain limits, an interim food additive regulation may be proposed in the FEDERAL REGISTER. This will permit further scientific investigations to define the conditions of safe use for a food additive regulation of indefinite duration.

§ 570.35 Affirmation of generally recognized as safe (GRAS) status.

(a) The Commissioner, either on his initiative or on the petition of an interested person, may affirm the GRAS status of substances that directly or indirectly become components of food.

(b) (1) If the Commissioner proposes on his own initiative that a substance is

entitled to affirmation as GRAS, he will place all of the data and information on which he relies on public file in the office of the Hearing Clerk and will publish in the FEDERAL REGISTER a notice giving the name of the substance, its proposed uses, and any limitations proposed for purposes other than safety.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Hearing Clerk. Copies of all comments received shall be made available for examination in the Hearing Clerk's office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is convincing evidence that the substance is GRAS as defined in § 570.3 (k), he will publish a notice in the FEDERAL REGISTER listing the substance in this subchapter E as GRAS.

(4) If, after evaluation of the comments, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS and that it should be considered a food additive subject to section 409 of the act, he shall publish a notice thereof in the FEDERAL REGISTER in accordance with § 570.38.

(c) (1) Persons seeking the affirmation of GRAS status of substances as provided for in § 570.30(e), except those subject to the NAS-NRC GRAS list survey (36 FR 20546), shall submit to the Commissioner of Food and Drugs a petition for GRAS affirmation in quadruplicate. Such petition shall contain information to establish that the GRAS criteria as set forth in § 570.30(b) have been met, in the following form:

(i) Description of the substance, including:

- (a) Common or usual name.
- (b) Chemical name.
- (c) Chemical Abstract Service (CAS) registry number.
- (d) Empirical formula.
- (e) Structural formula.
- (f) Specifications for food grade material, including arsenic and heavy metals. (Recommendation for any change in the Food Chemicals Codex monograph should be included where applicable.)

(g) Quantitative compositions.

(h) Manufacturing process (excluding any trade secrets).

(i) Use of the substance, including:

- (a) Date when use began.
- (b) Information and reports or other data on past uses in food.
- (c) Foods in which used, and levels of use in such foods, and for what purposes.
- (iii) Methods for detecting the substance in food, including:

(a) References to qualitative and quantitative methods for determining the substance(s) in food, including the type of analytical procedures used.

(b) Sensitivity and reproducibility of such method(s).

(iv) Information to establish the safety and functionality of the substance in food. Published scientific literature, evi-

dence that the substance is identical to a GRAS counterpart of natural biological origin, and other data may be submitted to support safety. Any adverse information or consumer complaints shall be included. Complete bibliographic references shall be provided where a copy of the article is not provided.

(v) A statement signed by the person responsible for the petition that to the best of his knowledge it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the safety and functionality of the substance.

(2) Within 30 days after the date of filing the petition, the Commissioner will place the petition on public file in the office of the Hearing Clerk and will publish a notice of filing in the FEDERAL REGISTER giving the name of the petitioner and a brief description of the petition including the name of the substance, its proposed use, and any limitations proposed for reasons other than safety. A copy of the notice will be mailed to the petitioner at the time the original is sent to the FEDERAL REGISTER.

(3) The notice of filing in the FEDERAL REGISTER will allow a period of 60 days during which any interested person may review the petition and/or file comments with the Hearing Clerk. Copies of all comments received shall be made available for examination in the Hearing Clerk's office.

(4) The Commissioner will evaluate the petition and all available information including all comments received. If the petition and such information provide convincing evidence that the substance is GRAS as defined in § 570.3, he will publish an order in the FEDERAL REGISTER listing the substance in this subchapter E as GRAS.

(5) If, after evaluation of the petition and all available information, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS and that it should be considered a food additive subject to section 409 of the act, he shall publish a notice thereof in the FEDERAL REGISTER in accordance with § 570.38.

(Sec. 201, 72 Stat. 1784-1788; 21 U.S.C. 321)

§ 570.38 Determination of food additive status.

(a) The Commissioner may, in accordance with § 570.35(b) (4) or (c) (5), publish a notice in the FEDERAL REGISTER determining that a substance is not GRAS and is a food additive subject to section 409 of the act.

(b) (1) The Commissioner may, on his own initiative, or on the basis of a petition establishing reasonable grounds therefor in accordance with § 571.130 of this chapter filed in quadruplicate by an interested person, publish a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the act. The Commissioner will place all of the data and information on which he relies on public file in the

office of the Hearing Clerk and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Hearing Clerk. Copies of all comments shall be made available for examination in the Hearing Clerk's office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the act, he will publish a notice thereof in the FEDERAL REGISTER. If he concludes that there is convincing evidence that the substance is GRAS, he will publish an order in the FEDERAL REGISTER listing the substance in this subchapter E as GRAS.

(c) A FEDERAL REGISTER notice determining that a substance is a food additive shall provide for the use of the additive in food or food-contact surfaces as follows:

(1) It may promulgate a food additive regulation governing use of the additive.

(2) It may promulgate an interim food additive regulation governing use of the additive.

(3) It may require discontinuation of the use of the additive.

(4) It may adopt any combination of the above three approaches for different uses or levels of use of the additive.

(Sec. 201, 72 Stat. 1784-1788; 21 U.S.C. 321)

PART 571—FOOD ADDITIVE PETITIONS

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AUTHORITY: Secs. 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions**§ 571.1 Petitions.**

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the act shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's post office address to which published notices or orders issued or objections filed pursuant to section 409 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food-additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

(Date)
Name of petitioner -----
Post office address -----
Date -----
Name of food additive and proposed use -----

Food and Drug Administration
BUREAU OF VETERINARY MEDICINE,
Associate Director for Scientific Evaluation
(HFV-100), Rockville, MD 20852.

DEAR SIR: The undersigned, -----
submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to -----

(Name of the food additive and proposed use)

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the food additive, its physical, chemical, and biological properties, and specifications prescribing the minimum content of the desired component(s) and identifying and limiting the reaction byproducts and other impurities. Where such information is not available, a statement as to the reasons why it is not should be submitted.

When the chemical identity and composition of the food additive is not known, the petition shall contain information in sufficient detail to permit evaluation regarding the method of manufacture and the analytical controls used during the various stages

of manufacturing, processing, or packing of the food additive which are relied upon to establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls within reasonable limits that do not affect the characteristics of the substance or the reliability of the controls may be specified.

If the food additive is a mixture of chemicals, the petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common English name and complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a food additive, the petition shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to ensure the identity, strength, quality, or purity of the additive, the expiration date that will be employed.

B. The amount of the food additive proposed for use and the purposes for which it is proposed, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the food additive and any labeling that will be required by applicable provisions of the Federal Food, Drug, and Cosmetic Act on the finished food by reason of the use of the food additive. If the additive results or may reasonably be expected to result from the use of packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

(Typewritten or other draft-labeling copy will be accepted for consideration of the petition, provided a statement is made that final printed labeling identical in content to the draft copy will be submitted as soon as available and prior to the marketing of the food additive.)

If the food additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance.)

C. Data establishing that the food additive will have the intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food and the amount necessary to accomplish this. These data should include information in sufficient detail to permit evaluation with control data.

D. A description of practicable methods to determine the amount of the food additive in the raw, processed, and/or finished food and of any substance formed in or on such food because of its use. The test proposed shall be one that can be used for food-control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel.

E. Full reports of investigations made with respect to the safety of the food additive.

(A petition may be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the food additive will be safe for its intended use. The reports ordinarily should

include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any reports of investigations that would bias an evaluation of the safety of the food additive.)

F. Proposed tolerances for the food additive, if tolerances are required in order to ensure its safety. A petitioner may include a proposed regulation.

G. If submitting petition to modify an existing regulation issued pursuant to section 409(c)(1)(A) of the act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

H. The petitioner is required to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the food additive pursuant to § 6.1 of this chapter.

Yours very truly,

Petitioner -----

By -----

(Indicate authority)

(d) The petitioner will be notified of the date on which his petition is filed, and an incomplete petition, or one that has not been submitted in triplicate, will usually be retained but not filed as a petition under section 409 of the act. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier. If part of the data have been submitted by the manufacturer of the food additive as a master file, the petitioner may refer to the master file if and to the extent he obtains the manufacturer's written permission to do so. The manufacturer may authorize specific reference to the data without disclosure to the petitioner. Nothing herein shall prevent reference to published data.

(g) A petition shall be retained but shall not be filed if any of the data prescribed by section 409(b) of the act are lacking or are not set forth so as to be readily understood.

(h)(1) The following data and information in a food additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(i) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(ii) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 4.61 of this chapter.

(iii) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(a) Names and any information that would identify the person using the product.

(b) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) A list of all ingredients contained in a food additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 4.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(v) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

(2) The following data and information in a food additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter:

(i) Manufacturing methods or processes, including quality control procedures.

(ii) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(iii) Quantitative or semiquantitative formulas.

(3) All correspondence and written summaries of oral discussions relating to a food additive petition are available for public disclosure in accordance with the provisions of Part 4 of this chapter when the food additive regulation is published in the FEDERAL REGISTER.

(4) For purposes of this regulation, safety and functionality data include all studies and tests of a food additive on animals and humans and all studies and tests on a food additive for identity, stability, purity, potency, performance, and usefulness.

(i) (1) Within 15 days after receipt, the Commissioner will notify the petitioner of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of the notification letter sent to petitioner becomes the date of filing for the purposes of section 409(b) (5) of the act. If the petitioner desires, he may

supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing.

(2) The Commissioner will publish in the FEDERAL REGISTER within 30 days from the date of filing of such petition, a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. In the case of a food additive which becomes a component of food by migration from packaging material, the notice shall include the name of the migratory substance, and where it is different from that of one of the original components, the name of the parent component, the maximum quantity of the migratory substance that is proposed for use in food, and the physical or other technical effect which the migratory substance or its parent component is intended to have in the packaging material. A copy of the notice will be mailed to the petitioner when the original is forwarded to the FEDERAL REGISTER for publication.

(j) The Commissioner may request a full description of the methods used in, and the facilities and controls used for, the production of the food additive, or a sample of the food additive, articles used as components thereof, or of the food in which the additive is proposed to be used, at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the food additive, or articles used as components thereof, or of the food in or on which the additive is proposed to be used, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the food additive present in foods for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the food additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 409(c) (2) of the act shall be moved forward 1 day for each day after the mailing date of the request taken by the petitioner to submit the sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

§ 571.6 Amendment of petition.

After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. Where

the substantive amendment proposes a substantial change to the petition which may affect the quality of the human environment, the petitioner is required to submit an environmental impact analysis report pursuant to § 6.1 of this chapter.

§ 571.7 Withdrawal of petition without prejudice.

(a) In some cases the Commissioner will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(b) At any time before the order provided for in § 571.100(a) has been forwarded to the FEDERAL REGISTER for publication, the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling the time limitation will begin to run anew.

Subpart B—Administrative Actions on Applications

§ 571.100 Regulation based on petition.

(a) The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 409(c) (2) of the act), a regulation prescribing the conditions under which the food additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and prior to the forwarding of the order to the FEDERAL REGISTER for publication shall notify the petitioner of such order and the reasons for such action; or by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(b) If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

§ 571.102 Effective date of regulation.

A regulation published in accordance with § 571.100(a) shall become effective upon publication in the FEDERAL REGISTER.

§ 571.110 Objection to regulation and request for hearing.

(a) Objections to an order promulgated pursuant to section 409(f) (1) of

the act shall be submitted in quintuplicate to the Hearing Clerk, Food and Drug Administration, at the address specified in such order. Each objection to a provision of the regulation shall be separately numbered.

(b) A statement of objections shall not be accepted for filing if:

(1) It is received for filing more than 30 days after the date of publication of the order in the *FEDERAL REGISTER*.

(2) It fails to establish that the objector will be adversely affected by the regulation.

(3) It does not specify with particularity the provisions of the regulation to which objection is taken.

(4) It does not state reasonable grounds for each objection raised. Grounds that it is reasonable to conclude are capable of being established by reliable evidence at the hearing, and which if proved would call for changing the provisions specified in the objections, will be deemed reasonable grounds.

(c) If the statement of objections may not be filed, the Commissioner shall inform the objector of the reasons.

(d) If objections to a regulation issued pursuant to the filing of a petition are filed by a person other than the petitioner, the Food and Drug Administration shall send a copy of the objections by certified mail to the petitioner at the address given in the petition. Petitioner shall have 2 weeks from the date of receipt by him of the objections to make written reply.

§ 571.120 Request for stay of effective date of regulation pending a hearing.

When a hearing is requested under § 571.110, the request may also include a request for a stay of effectiveness of the order, in whole or in part, which request shall include the reasons for the stay together with a showing that the stay involves no hazard to the public health.

§ 571.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner or any interested person may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exemption for such additive. Such a proposal by an interested person shall be in writing. If such proposal by an interested person furnishes reasonable grounds therefor the Commissioner will publish a notice announcing the proposal. Proposals initiated by the Commissioner will likewise be published. Following such publication, the proceedings shall be the same as prescribed by section 409 of the act and the regulations in this part for the promulgation of a regulation.

(b) "Reasonable grounds" shall include an explanation showing wherein the person has a substantial interest in such regulation and an assertion of facts (supported by data if available) showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experi-

ence with the existing regulation or exemption may justify its amendment or repeal. New data should be furnished in the form specified in § 571.1 for submitting petitions.

Subpart C—Hearing Procedures

§ 571.200 Notice of public hearing.

If the objections and statements filed by any person when they are considered with the record in the proceeding (including any reply to the objections that the petitioner may have filed), show that the person filing the objections is adversely affected and that the grounds stated in support of the objections are reasonable, and a public hearing on the objections is requested, the Commissioner shall cause to be published in the *FEDERAL REGISTER* a notice reciting the objections and announcing a public hearing to receive evidence on them. The notice shall designate the place where the hearing will be held, specify the time within which appearances must be filed, and specify the time (not earlier than 30 days after the date of publication of the notice in the *FEDERAL REGISTER*) when the hearing will commence. The hearing will convene at the place and time announced in the notice, but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without other notice than announcement thereof by the presiding officer at the hearing. Included in such notice shall be a statement indicating whether the regulation to which objection was taken shall be stayed pending the outcome of the hearing.

§ 571.202 Appearances and burden of proof at public hearing.

At the hearing, the person whose objections raised the issues to be determined shall be, within the meaning of section 7(c) of the Administrative Procedure Act, the proponent of the order sought, and accordingly shall have the burden of proof. Any interested person shall be given an opportunity to appear at the hearing, either in person or by his authorized representative, and to be heard with respect to matters relevant to the issues raised by the objections. Any interested person who desires to be heard at the hearing in person or through a representative shall, within the time specified in the notice of hearing, file with the presiding officer a written notice of appearance setting forth his name, address, and employment. If such person desires to be heard through a representative, such person or such representative shall file with the presiding officer a written appearance setting forth the name, address, and employment of such person. Any person or representative shall state with particularity in the notice of appearance his interest in the proceeding and shall set forth the specific provisions of the regulation concerning which objections have been made on which such person desires to be heard. The notice of appearance shall also set forth with particularity the position to be taken concerning the

objections on which he wishes to be heard. No person shall be heard if he failed to file notice of his appearance within the time prescribed, in the absence of a clear showing of good cause why the notice of appearance was not filed. All present at the hearing shall conform to all reasonable standards of orderly and ethical conduct.

§ 571.203 Administrative Law Judge.

The hearing shall be conducted by an Administrative Law Judge, who shall be an Administrative Law Judge appointed as provided in the Administrative Procedure Act (sec. 11, 60 Stat. 244, as amended; 5 U.S.C. 1010 et seq.) and designated by the Commissioner for conducting the hearing. Any such designation may be made or revoked by the Commissioner at any time. Hearings shall be conducted in an informal but orderly manner in accordance with the regulations in this part and the requirements of the Administrative Procedure Act. The Administrative Law Judge shall have the power to administer oaths and affirmations, to rule upon offers of proof and admissibility of evidence, to receive relevant evidence, to examine witnesses, to regulate the course of the hearing, to hold conferences for the simplification of the issues, and to dispose of procedural requests, but he shall not have power to decide any motion that involves final determination of the merits of the proceeding.

§ 571.204 Prehearing and other conferences.

(a) The Administrative Law Judge, on his own motion or on the motion of any party or his representative, may direct all parties or their representatives to appear at a specific time and place for a prehearing conference to consider:

- (1) The simplification of the issues.
- (2) The possibility of obtaining stipulations, admissions of facts, and documents.
- (3) The possibility of the limitation of the number of witnesses.
- (4) The scheduling of witnesses to be called.
- (5) The advance submission of all documentary evidence.
- (6) Such other matters as may aid in the disposition of the proceeding.

The Administrative Law Judge shall make an order reciting the action taken at the conference, the agreements made by the parties or their representatives, and the scheduling of witnesses, and limiting the issues for hearing to those not disposed of by admissions or agreements. Such order shall control the subsequent course of the proceeding unless modified for good cause by subsequent order.

(b) The Administrative Law Judge may also direct all parties and their representatives to appear at conferences at any time during the hearing with a view to simplification, clarification, or shortening of the hearing.

§ 571.205 Transcript of the testimony.

Testimony given at a public hearing shall be reported verbatim. All written

statements, charts, tabulations, and similar data offered in evidence at the hearing shall be marked for identification and, upon a showing satisfactory to the presiding officer of their authenticity, relevancy, and materiality, shall be received in evidence subject to the Administrative Procedure Act (sec. 7(c), 60 Stat. 238; 5 U.S.C. 1008(c)). Exhibits shall if practicable, be submitted in quintuplicate. In case the required number of copies are not made available, the Administrative Law Judge shall exercise his discretion in determining whether said exhibit shall be read in evidence or whether additional copies shall be required to be submitted within a time to be specified by the Administrative Law Judge. Where the testimony of a witness refers to a statute, or to a report or document, the Administrative Law Judge shall, after inquiry relating to the identification of such statute, report, or document, determine whether the same shall be produced at the hearing and physically be made a part of the evidence by reference. Where relevant and material matter offered in evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter shall be excluded and shall be segregated insofar as practicable, subject to the direction of the Administrative Law Judge.

§ 571.206 Oral and written arguments.

(a) Unless the Administrative Law Judge issues an announcement at the hearing authorizing oral argument before him, it shall not be permitted.

(b) The Administrative Law Judge shall announce at the hearing a reasonable period within which interested persons may file written arguments based solely upon the evidence received at the hearing, citing the pages of the transcript of the testimony or properly identified exhibits where such evidence occurs.

§ 571.208 Index of hearing record.

(a) Whenever it appears to the Administrative Law Judge that the record of hearing will be of such length that an index to the record will permit a more orderly analysis of the evidence and reduce delay, the Administrative Law Judge shall require counsel for the parties to prepare a daily topical index, which will be available to the Administrative Law Judge and all parties. Preparation of such an index shall be apportioned among all counsel present in such manner as appears just and proper in the circumstances.

(b) The index shall include each topic of testimony upon which evidence is taken, the name of each witness testifying upon the topic, the page of the record at which each portion of his testimony appeared, and the number of each exhibit relating to the topic. The index shall also contain the name of each witness, followed by the topics upon which he testified and the page of the record at which such testimony appears.

§ 571.210 Certification of hearing record.

At the close of the hearing, the Administrative Law Judge shall afford witnesses and their counsel a short time (not longer than 30 days, except in unusual cases) in which to point out errors that may have been made in transcribing the testimony. The Administrative Law Judge shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony and he shall certify the transcript of testimony and the exhibits to the Commissioner.

§ 571.212 Filing of hearing record.

As soon as practicable after the close of the hearing, the complete record of the hearing shall be filed in the office of the Hearing Clerk. The record shall include the transcript of the testimony, all exhibits, and any written arguments that may have been filed.

§ 571.214 Copies of hearing record.

The Department will make provision for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purposes. Any person desiring a copy of the record of the hearing or of any part thereof shall be entitled to the same upon payment of the costs thereof.

Subpart D—Evidence

§ 571.220 Submission of documents in advance of hearing.

(a) All documents to be offered at the hearing shall be submitted to the Administrative Law Judge and to the interested parties sufficiently in advance of the offer of such documents for introduction into the record to permit study and preparation of cross-examination and rebuttal evidence.

(b) The Administrative Law Judge, after consultation with the parties at a conference called in accordance with § 571.204, shall make an order specifying the time at which documents shall be submitted. He shall also specify in his order the time within which objection to the authenticity of such documents must be made to comply with paragraph (d) of this section.

(c) Documents not submitted in advance in accordance with the requirements of paragraphs (a) and (b) of this section shall not be received in evidence in the absence of a clear showing that the offering party had good cause for his failure to produce the documents sooner.

(d) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the Administrative Law Judge upon notice to the other parties within the time specified by the Administrative Law Judge in accordance with paragraph (b) of this section, except that a party will be permitted to challenge such authenticity at a later time upon a clear showing of good cause for failure to have filed such written objection.

§ 571.221 Excerpts from documents.

When portions only of a document are to be relied upon, the offering party shall prepare the pertinent excerpts, adequately identified, and shall supply copies of such excerpts, together with a statement indicating the purpose for which such materials will be offered, to the Administrative Law Judge and to the other parties. Only the excerpts, so prepared and submitted, shall be received in the record. However, the whole of the original document should be made available for examination and for use by opposing counsel for purposes of cross-examination.

§ 571.222 Submission and receipt of evidence.

(a) Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) When necessary to prevent undue prolongation of the hearing, the Administrative Law Judge may limit the number of times any witness may testify, the repetitious examination and cross-examination of witnesses, or the amount of corroborative or cumulative evidence.

(c) The Administrative Law Judge shall admit only evidence which is relevant, material, and not unduly repetitious.

(d) Opinion evidence shall be admitted when the Administrative Law Judge is satisfied that the witness is properly qualified.

(e) The Administrative Law Judge shall file as an exhibit a copy of the FEDERAL REGISTER promulgating the regulation to which objections were taken and the objections that form the basis for the hearing. All documents constituting the record bearing on the point in controversy, and not entitled to protection under section 301(j) of the act, accumulated up to the start of the hearing shall be open for inspection by interested persons during office hours in the office of the Hearing Clerk, Food and Drug Administration, Parklawn Bldg., Rm. 465, 5600 Fishers Lane, Rockville, Md. 20852.

(f) If any person objects to the admission or rejection of any evidence or to other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection, and the transcript shall not include extended argument or debate thereon except as ordered by the presiding officer. A ruling of the Administrative Law Judge on any such objection shall be a part of the transcript, together with such offer of proof as has been made.

Subpart E—Findings of Facts and Order

§ 571.230 Proposed order after public hearing.

As soon as practicable after the time for filing written arguments has ended the Commissioner shall prepare and cause to be published in the FEDERAL REGISTER a proposed order which shall set forth in detail the findings of fact

and conclusions, and recommend decision on the objections that were the subject of the hearing and tentative regulations. The proposed order shall specify a reasonable time, ordinarily not to exceed 60 days, within which any interested person may file exceptions. The exceptions shall point out with particularity the alleged errors in said proposed order and shall contain a specific reference to the pages of the transcript of the testimony or to the exhibits on which each exception is based. Such exceptions may be accompanied by a memorandum or brief.

§ 571.232 Final order after public hearing.

As soon as practicable after the time for filing exceptions has passed, the record and the exceptions shall be presented to the Secretary and he shall cause to be published in the FEDERAL REGISTER his final order promulgating the regulation, which shall specify the date on which the order shall take effect.

Subpart F—Judicial Review

§ 571.235 Judicial review.

The Secretary of Health Education and Welfare hereby designates the Assistant General Counsel for Food and Drugs of the Department of Health, Education, and Welfare as the officer upon whom copy of petition for judicial review shall be served. Such officer shall be responsible for filing in the court a transcript of proceedings and the record on which the order of the Secretary of Health, Education, and Welfare is based. The transcript and record shall be certified by the Secretary.

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

Subpart A—[Reserved]

Subpart B—Food Additive Listing

Sec.	
573.120	Acrylamide-acrylic acid resin.
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573.420	Ethyl cellulose.
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573.560	Iron ammonium citrate.
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573.600	Lignin sulfonated.
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573.640	Methyl esters of higher fatty acids.

573.660	Methyl glucoside-coconut oil ester.
573.680	Mineral oil.
573.700	Sodium nitrite.
573.720	Petrolatum.
573.740	Odorless light petroleum hydrocarbons.
573.760	Foloxalene.
573.780	Polyethylene.
573.800	Polyethylene glycol (400) mono- and dioleate.
573.820	Polyoxyethylene glycol (400) mono- and dioleates.
573.840	Polysorbate 80.
573.860	Polysorbate 80.
573.880	Normal propyl alcohol.
573.900	Pyrophosphite.
573.920	Selenium.
573.940	Silicon dioxide.
573.960	Sorbitan monostearate.
573.980	Taurine.
573.1000	Verxite.
573.1020	Yellow prussiate of soda.

AUTHORITY: Sec. 409, 72 Stat. 1785-1788 as amended (21 U.S.C. 348) unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Food Additive Listing

§ 573.120 Acrylamide-acrylic acid resin.

Acrylamide-acrylic acid resin (hydrolyzed polyacrylamide), only for the purposes of this section as described below, may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by polymerization of acrylamide with partial hydrolysis, or by copolymerization of acrylamide and acrylic acid with the greater part of the polymer being composed of acrylamide units.

(b) The additive meets the following specifications:

(1) Molecular Weight range: 3 to 6 million.

(2) Viscosity range: 3,000 to 6,000 centipoises at 77° F in a 1 percent aqueous solution as determined by LVF Brookfield Viscometer or equivalent using a number 6 spindle at 20 r.p.m.

(3) Residual acrylamide: Not more than 0.05 percent.

(c) It is used as a thickener and suspending agent in nonmedicated aqueous suspensions intended for addition to animal feeds.

§ 573.140 Ammoniated cottonseed meal.

The food additive ammoniated cottonseed meal may be safely used in accordance with the following conditions:

(a) The food additive is the product obtained by the treatment of cottonseed meal with anhydrous ammonia until a pressure of 50 pounds per square inch gauge is reached.

(b) It is used or intended for use in the feed of ruminants as a source of protein and/or as the sole source of non-protein nitrogen in an amount not to exceed 20 percent of the total ration.

(c) To assure safe use, the label and labeling of the additive and of any feed additive supplement, concentrate, or premix prepared therefrom shall bear, in addition to the other information required by the act, the following:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from the nonprotein nitrogen.

(3) Directions for use to provide not more than 20 percent of the additive in the total ration.

(4) A statement:

(i) That not more than one-third of the total protein in the feed should come from nonprotein nitrogen sources.

(ii) That the additive is not to be given to debilitated or starved animals.

(iii) "Warning—This feed should be used only in accordance with directions furnished on the label."

§ 573.160 Ammoniated rice hulls.

The food additive ammoniated rice hulls may be safely used in accordance with the following prescribed conditions:

(a) The food additive is the product obtained by the treatment of ground rice hulls with monocalcium phosphate and anhydrous ammonia at a temperature of 350° F and a pressure of 175 pounds per square inch.

(b) It is used or intended for use in the feed of beef cattle as a source of crude fiber and as the sole source of non-protein nitrogen in an amount not to exceed 20 percent of the total ration.

(c) To assure safe use of the additive, the label and labeling of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, shall contain, in addition to other information required by the act, the following:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from the non-protein nitrogen.

(3) Directions for use to provide not more than 20 percent of the additive in the total ration, and a prominent statement: "Warning—This feed should be used only in accordance with the directions furnished on the label."

§ 573.180 Anhydrous ammonia.

The food additive anhydrous ammonia may be safely used in accordance with the following conditions:

(a) The food additive is used as a component of an aqueous premix which includes ammonia, molasses and minerals so that the premix contains not less than 16 percent nor more than 17 percent ammonia and not less than 83 percent crude protein.

(b) The premix is used or intended for use for mixing with corn plant material prior to ensiling, as a source of non-protein nitrogen and minerals.

(c) To assure safe use, the label and labeling of the premix shall bear, in addition to the other information required by the act, the following:

(1) The name of the additive.

(2) A statement of the quantity of ammonia contained therein.

(3) The maximum percentage of equivalent crude protein from nonprotein nitrogen.

(4) An expiration date that is not more than 10 weeks following the date of its manufacture.

(5) A statement that silage treated with the additive is to be fed to cattle only.

(6) A statement that additional protein should not be fed to lactating dairy cows producing less than 32 pounds of milk per day, or beef cattle consuming less than 1 percent of body weight daily in shelled corn.

(7) A warning statement to read as follows: "Warning—Use only as directed; additional trace mineral supplementation should not be fed with treated silage."

§ 573.200 Condensed animal protein hydrolysate.

(a) *Identity.* The condensed animal protein hydrolysate is produced from the meat byproducts scraped from cured (salted) hides taken from cattle slaughtered for food consumption. The meat byproduct is hydrolyzed with heat and phosphoric acid.

(b) *Specifications.* The additive shall conform to the following percent-by-weight specifications:

Moisture, not less than 45 percent nor more than 50 percent.

Protein, not less than 24 percent.

Salt (NaCl), not more than 15 percent.

Phosphorus, not less than 2.25 percent.

(c) *Uses.* It is used or intended for use as a source of animal protein, phosphorus, and salt (NaCl) as follows:

(1) In poultry and swine feed in an amount not to exceed 5 percent by weight of the feed.

(2) In feed concentrates for cattle in an amount not to exceed 10 percent by weight of the concentrate.

(d) *Labeling.* The label and labeling shall bear, in addition to the other information required by the act:

(1) The name of the additive, condensed animal protein hydrolysate.

(2) Adequate directions for use including maximum quantities permitted for each species and a guaranteed analysis of the additive.

§ 573.220 Feed-grade biuret.

The food additive feed grade biuret may be safely used in ruminant feed in accordance with the following prescribed conditions:

(a) The food additive is the product resulting from the controlled pyrolysis of urea conforming to the following specifications:

	Percent
Biuret	55 minimum.
Urea	15 maximum.
Cyanuric acid and triuret	30 maximum.
Mineral oil	0.5 maximum.
Total nitrogen (equivalent to 218.75 pct crude protein).	35 minimum.

(b) It is used in ruminant feeds as a source of nonprotein nitrogen.

(c) To assure safe use of the additive:

(1) The label and labeling of the additive and that of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall contain, in addition to other information required by the act, the following:

(i) The name of the additive.

(ii) The maximum percentage of equivalent crude protein from nonprotein nitrogen.

(iii) The statement "Do not feed to animals producing milk for human consumption."

(2) The label shall recommend that the diet be balanced to provide adequate nutrients when equivalent crude protein from all forms of nonprotein nitrogen exceed one-third of the total crude protein in the total daily ration.

§ 573.240 Calcium periodate.

The food additive calcium periodate may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by reacting calcium iodate with calcium hydroxide or calcium oxide to form a substance consisting of not less than 60 percent by weight of penta calcium orthoperiodate containing 28 to 31 percent by weight of iodine.

(b) It is used or intended for use in salt for livestock as a source of iodine.

§ 573.260 Calcium silicate.

Calcium silicate, including synthetic calcium silicate, may be safely used as an anticaking agent in animal feed, provided that the amount of calcium silicate does not exceed 2 percent.

§ 573.280 Feed-grade calcium stearate.

Feed-grade calcium stearate may be safely used in an animal feed in accordance with the following prescribed conditions:

(a) Feed-grade calcium stearate is the calcium salt of a fatty acid mixture that is predominately stearic acid. Associated fatty acids, including palmitic acid and minor amounts of lauric, myristic, pentadecanoic, margaric, arachidic, and other fatty acids may be contained in the mixture, but such associated fatty acids in aggregate do not exceed 35 percent by weight of the mixture. The fatty acids may be derived from feed-grade fats or oils.

(b) The additive meets the following specifications:

(1) Unsaponifiable matter does not exceed 2 percent.

(2) It is free of chick-edema factor.

(c) The additive is manufactured so that in aqueous solution it is exposed for 1 hour or longer to temperature in excess of 180° F.

(d) It is used as an anticaking agent in animal feeds in accordance with good manufacturing practice.

§ 573.300 Choline xanthate.

Choline xanthate may be safely used as a component of animal feed as an added source of choline to supplement the diets of poultry, ruminants, and swine in accordance with good feeding practice.

§ 573.320 Diammonium phosphate.

The food additive diammonium phosphate may be safely used in ruminant feed in accordance with the following prescribed conditions:

(a) The food additive is the product resulting from the neutralization of feeding-phosphoric acid or defluorinated wet-process phosphoric acid with anhydrous ammonia. It contains not less than 106.25 percent equivalent crude protein (nitrogen X 6.25) and 20 percent phosphorus. It contains not more than the following:

1 part fluorine to 100 parts phosphorus.

75 parts per million or arsenic (as As).

30 parts per million of heavy metals, as lead (Pb).

(b) It is used in ruminant feeds as a source of phosphorus and nitrogen in an amount that supplies not more than 2 percent of equivalent crude protein in the total daily ration.

(c) To assure safe use of the additive, the label and labeling of the additive and that of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall contain, in addition to other information required by the act, the following:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from the nonprotein nitrogen.

(3) If the feed additive premix, feed additive concentrate, or feed additive supplement contains more than 2 percent equivalent crude protein from diammonium phosphate, adequate directions for use and a prominent statement, "Warning—This feed should be used only in accordance with directions furnished on the label."

§ 573.340 Diatomaceous earth.

(a) *Identity.* The additive consists of siliceous skeletal material derived from various species of diatoms.

(b) *Specifications.* The additive shall conform to the following specifications:

Lead, not more than 15 parts per million.

Arsenic (as As), not more than 20 parts per million.

Fluorine, not more than 600 parts per million.

(c) *Uses.* It is used or intended for use as an inert carrier or anticaking agent in animal feeds in an amount not to exceed 2 percent by weight of the total ration.

§ 573.360 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in animal feeds, in accordance with the following prescribed conditions:

(a) The food additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate ($C_{10}H_{16}O_8 \cdot 2H_2O$).

(b) It is used to solubilize trace minerals in aqueous solutions, which are then added to animal feeds.

(c) It is used or intended for use in an amount not to exceed 240 parts per million of the additive in finished feed.

(d) To assure safe use of the additive the label and labeling shall bear:

(1) The name of the additive; and

(2) Adequate mixing directions to ensure that the chelated trace-mineral mix is uniformly blended throughout the feed.

§ 573.380 Ethoxyquin in animal feeds.

Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used in animal feeds, when incorporated therein in accordance with the following prescribed conditions.

(a) It is intended for use only: (1) As a chemical preservative for retarding oxidation of carotene, xanthophylls, and vitamins A and E in animal feed and fish food and, (2) as an aid in preventing the development of organic peroxides in canned pet food.

(b) The maximum quantity of the additive permitted to be used and to remain in or on the treated article shall not exceed 150 parts per million.

(c) To assure safe use of the additive, the label and labeling of the food additive container and that of any intermediate premixes prepared therefrom shall contain, in addition to other information required by the act:

(1) The name of the additive, ethoxyquin.

(2) A statement of the concentration or strength contained therein.

(3) Adequate use directions to provide for a finished article with the proper concentration of the additive as provided in paragraph (b) of this section, whether or not intermediate premixes are to be used.

(d) The label of any animal feed containing the additive shall, in addition to the other information required by the act, bear the statement "Ethoxyquin, a preservative" or "Ethoxyquin added to retard the oxidative destruction of carotene, xanthophylls, and vitamins A and E."

§ 573.400 Ethoxyquin in certain dehydrated forage crops.

Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used in the dehydrated forage crops listed in paragraph (a) of this section when incorporated therein in accordance with the conditions prescribed in this section:

(a) It may be added to dehydrated forage prepared from:

Alfalfa.....	Medicago sativa.
Barley.....	Hordeum vulgare.
Clovers:	
Alsike clover.....	Trifolium hybridum.
Crimson clover.....	Trifolium incarnatum.
Red clover.....	Trifolium pratense.
White clover (including Ladino).....	Trifolium repens.
White sweetclover.....	Melilotus alba.
Yellow sweetclover.....	Melilotus officinalis.
Coastal Bermudagrass.....	Cynodon dactylon.
Corn.....	Zea mays.
Fescue.....	Festuca sp.
Oats.....	Avena sativa.
Orchardgrass.....	Dactylis glomerata.
Reed canarygrass.....	Phalaris arundinacea.
Ryegrass (annual and perennial).....	Elymus sp. and Lolium perenne.
Sorghums.....	Sorghum vulgare var. feterita, shalu, kaoliang, broomcorn.

Sudan grass.....	Sorghum vulgare sudanense.
Wheat.....	Triticum aestivum.

or any mixture of such forage crops, for use only as an animal feed.

(b) Such additive is used only as a chemical preservative for the purpose of retarding oxidative destruction of naturally occurring carotenes and vitamin E in the forage crops.

(c) It is added to the dehydrated forage crops in an oil mixture containing only suitable animal or suitable vegetable oil, prior to grinding and mixing.

(d) The maximum quantity of the additive permitted to be used and to remain in or on the dehydrated forage crop shall not exceed 150 parts per million.

(e) To assure the safe use of the additive, the label of the market package shall contain, in addition to other information required by the act:

(1) The name of the additive as specified in this section.

(2) Directions for the incorporation of the additive in the forage crops, as specified in paragraph (c) of this section, with the directive that only suitable animal or suitable vegetable oils are to be used in the oil mix.

(f) The label of any dehydrated forage crops treated with the additive or the label of an animal-feed supplement containing such treated forage crops, shall, in addition to other information required by the act, bear the following statements:

(1) "Ethoxyquin, a preservative," or "Ethoxyquin added to retard the oxidative destruction of carotene and vitamin E."

(2) The statement "For use in animal feed only."

§ 573.420 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in animal feed in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC₂H₅) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

(b) It is used or intended for use as a binder or filler in dry vitamin preparations to be incorporated into animal feed.

§ 573.440 Ethylene dichloride.

The food additive ethylene dichloride may be safely used in the manufacture of animal feeds in accordance with the following prescribed conditions:

(a) It is used as a solvent in the extraction processing of animal byproducts for use in animal feeds.

(b) The maximum quantity of the additive permitted to remain in or on the extracted byproducts shall not exceed 300 parts per million.

(c) The extracted animal byproduct is added as a source of protein to a total ration at levels consistent with good feeding practices, but in no event at levels exceeding 13 percent of the total ration.

§ 573.460 Formaldehyde.

The food additive formaldehyde may be safely used in the manufacture of animal feeds in accordance with the following conditions:

(a) The additive is used, or intended for use, to improve the handling characteristics of animal fat in combination with certain oilseed meals by producing therefrom a dry, free-flowing product as follows:

(1) An aqueous blend of soybean and sunflower meals in a ratio of 3:1, respectively, is mixed with animal fat such that the oilseed meals and animal fat are in a ratio of 3:2. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 1976 ed., pages 86, 103, and 109.¹

(2) Formaldehyde (37 percent solution) is added to the mixture at a level of 4 percent of the dry matter weight of the oilseed meals and animal fat. This mixture, upon drying, contains not more than 1 percent formaldehyde and not more than 12 percent moisture.

(b) The dried mixture described in paragraph (a) of this section is used, or intended for use, as a component of dry, nonpelleted feeds for beef and nonlactating dairy cattle.

(c) To assure safe use of the additive, in addition to the other information required by the act, the label and labeling of the dried mixture described in paragraph (a) of this section shall bear:

(1) The name of the additive.

(2) Adequate directions for use providing that feed as consumed is not to contain more than 25 percent of the mixture.

§ 573.480 Formic acid.

Formic acid may be safely used as a preservative in hay crop silage in an amount not to exceed 2.25 percent of the silage on a dry weight basis or 0.45 percent when direct-cut. The top foot of silage stored should not contain formic acid and silage should not be fed to livestock within 4 weeks of treatment.

§ 573.500 Condensed, extracted glutamic acid fermentation product.

Condensed, extracted glutamic acid fermentation product may be safely used in animal feed under the following conditions:

(a) The additive is a concentrated mixture of the liquor remaining from the extraction of glutamic acid, combined with the cells of *Corynebacterium lilium* used to produce the glutamic acid.

(b) It is used or intended for use as follows:

(1) In poultry feed as a source of protein in an amount not to exceed 5 percent of the total ration.

(2) In cattle feed as a source of protein in an amount not to exceed 10 percent of the feed.

(c) In order to assure safe use, the

¹ Copies may be obtained from: Ernest A. Epps, Jr., Treasurer, Division of Agricultural Chemistry, P.O. Box 16390-A, Baton Rouge, LA 70803.

label and labeling of the additive shall bear, in addition to the other information required by the act, the following:

- (1) The name of the additive.
- (2) A statement of the concentration of the additive contained in any mixture.
- (3) Adequate directions for use.

§ 573.520 Hemicellulose extract.

Hemicellulose extract may be safely used in animal feed when incorporated therein in accordance with the following conditions:

(a) The additive is produced from the aqueous extract obtained by the treatment of wood with water at elevated temperatures (420°-535° F) and pressure (300-900 pounds per square inch) and contains primarily pentose and hexose sugars.

(b) The additive may be used in a liquid or dry state with the liquid product containing not less than 55 percent carbohydrate and the dry product containing not less than 84 percent carbohydrate.

(c) The additive is used as a source of metabolizable energy in animal feed in accordance with good manufacturing and feeding practices.

§ 573.540 Hydrolyzed leather meal.

(a) *Identity.* Hydrolyzed leather meal is produced from leather scraps that are treated with steam for not less than 33 minutes at a pressure of not less than 125 pounds per square inch.

(b) *Specifications.* The additive shall conform to the following percent-by-weight specifications:

Moisture, not less than 5 percent nor more than 10 percent.
Crude protein, not less than 60 percent.
Crude fat, not less than 5 percent.
Crude fiber, not more than 6 percent.
Chromium, not more than 2.75 percent.

(c) *Use.* It is used or intended for use as a source of protein in swine feeds in an amount not to exceed 1.0 percent by weight of the finished feed.

(d) *Labeling.* The labels and labeling shall bear, in addition to the other information required by the act:

- (1) The name of the additive, hydrolyzed leather meal.
- (2) Adequate directions to provide finished feeds complying with paragraph (c) of this section.

§ 573.560 Iron ammonium citrate.

Iron ammonium citrate may be safely used in animal feed in accordance with the following prescribed conditions:

(a) The additive is the chemical green ferric ammonium citrate.

(b) The additive is used or intended for use as an anticaking agent in salt for animal consumption so that the level of iron ammonium citrate does not exceed 25 parts per million (0.0025 percent) in the finished salt.

(c) To assure safe use of the additive the label or labeling of the additive shall bear, in addition to the other information required by the act:

- (1) The name of the additive.
- (2) Adequate directions to provide a final product that complies with the

limitations prescribed in paragraph (b) of this section.

§ 573.580 Iron-choline citrate complex.

Iron-choline citrate complex made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in animal feed.

§ 573.600 Lignin sulfonates.

Lignin sulfonates may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) For the purpose of this section, the food additive is either one, or a combination of, the ammonium, calcium, magnesium, or sodium salts of the extract of spent sulfite liquor derived from the sulfite digestion of wood or of abaca (*Musa textilis*) or of sisal (*Agave sisalana*) in either a liquid form (moisture not to exceed 50 percent by weight) or dry form (moisture not to exceed 6 percent by weight).

(b) It is used or intended for use in an amount calculated on a dry weight basis, as follows:

(1) As a pelleting aid in the liquid or dry form in an amount not to exceed 4 percent of the finished pellets.

(2) As a binding aid in the liquid form in the flaking of feed grains in an amount not to exceed 4 percent of the flaked grain.

(3) As a surfactant in molasses used in feeds, as liquid lignin sulfonate, in an amount not to exceed 11 percent of the molasses.

(4) As a source of metabolizable energy, in the liquid or dry form, in an amount not to exceed 4 percent of the finished feed.

§ 573.620 Menadione dimethylpyrimidinol bisulfite.

The food additive, menadione dimethylpyrimidinol bisulfite, may be safely used in accordance with the following conditions:

(a) The additive is the 2-hydroxy-4, 6-dimethylpyrimidinol salt of menadione ($C_{11}H_{10}O_5NS$).

(b) The additive is used or intended for use as a nutritional supplement for the prevention of vitamin K deficiency as follows:

(1) In chicken and turkey feed at a level not to exceed 2 grams per ton of complete feed.

(2) In the feed of growing and finishing swine at a level not to exceed 10 grams per ton of feed.

(c) To assure safe use, the label and labeling of the additive shall bear adequate directions for use.

§ 573.640 Methyl esters of higher fatty acids.

The food additive methyl esters of higher fatty acids may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reaction of methyl alcohol with feed-grade fats or oils and consists of not less than 70 percent methyl esters of the following straight-chain monocarboxylic

acids: Docosahexanoic acid, eicosapentanoic acid, linoleic acid, myristic acid, oleic acid, palmitic acid, palmitoleic acid, and stearic acid, and lesser amounts of the associated acid esters.

(b) The food additive meets the following specifications:

(1) Free methyl alcohol not to exceed 150 parts per million.

(2) Unsaponifiable matter not to exceed 2 percent.

(3) It is free of chick-edema factor or other factors toxic to chicks, as evidenced during the bioassay method for determining the chick-edema factor as prescribed in paragraph (b) (4) (ii) of this section.

(4) For the purposes of this section:

(i) Unsaponifiable matter shall be determined by the method described in section 26.049, Official Methods of Analysis of the Association of Official Agricultural Chemists, 9th Ed. (1960).¹

(ii) The chick-edema factor bioassay method described in the Journal of the Association of Official Agricultural Chemists, Volume 44, page 146 (1961),¹ shall be employed. The presence of chick-edema factor shall be determined by a comparison between the mean log of the pericardial fluid volumes of a test group and of a concurrent negative control group. The significance of the difference in pericardial fluid volumes between the test group and the negative control group is determined by calculating a "t" value according to the formula:

$$t = \frac{\bar{x}_t - \bar{x}_c}{\sqrt{\frac{s_t^2}{n_t} + \frac{s_c^2}{n_c}}}$$

where:

$\bar{x}_t$ and $\bar{x}_c$ are the means of the logs of the pericardial fluid volumes of the test and control groups, respectively;

n_t and n_c are the number of chicks in the respective groups;

s_t^2 and s_c^2 are the variances of the test and control groups, respectively.

The variances are calculated as follows:

$$s^2 = \frac{n(\sum x^2) - (\sum x)^2}{n(n-1)}$$

where:

$\sum x$ is the sum of the logs of the pericardial fluid volumes;

$\sum x^2$ is the sum of the squares of the logs of the pericardial fluid volumes for either the test t or control c group data.

The test sample is judged to contain chick-edema factor if the calculated "t" exceeds +1.3 and the mean log of the pericardial fluid volume obtained from the negative control group multiplied by 100 is less than 1.1461.

(iii) "Other factors toxic to chicks" referred to in paragraph (b) (3) of this section shall be determined during the course of the bioassay test described in paragraph (b) (4) (ii) of this section, on the basis of chick deaths or other abnor-

¹ Copies are available from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

malities not attributable to chick-edema factor or to the experimental conditions of the test.

(c) It is used or intended for use as a supplementary source of fat for animal feed.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive, and any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear:

(i) The name of the additive.

(ii) The designation "feed grade" in juxtaposition with the name and equally as prominent.

(2) The label or labeling of the additive and any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear adequate directions for use.

§ 573.660 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in accordance with the following conditions:

(a) The additive meets the specifications prescribed in § 121.1151 of this chapter.

(b) It is used as a surfactant in molasses intended for use in animal feed at a level not to exceed 320 parts per million.

§ 573.680 Mineral oil.

Mineral oil may be safely used in animal feed, subject to the provisions of this section.

(a) Mineral oil, for the purpose of this section, is that complying with the definition and specifications contained in § 121.1146 (a) and (b) or in § 121.2589 (b) (1) (i) and (ii) of this chapter.

(b) It is used in animal feeds for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks and to improve resistance to moisture of such pellets, cubes, or blocks.

(3) To prevent the segregation of trace minerals in mineralized salt.

(4) To serve as a diluent carrier in the manufacture of feed grade biuret in accordance with good manufacturing practice.

(c) The quantity of mineral oil used in animal feed shall not exceed 3.0 percent in mineral supplements, nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

§ 573.700 Sodium nitrite.

Sodium nitrite may be safely used in canned pet food containing meat and fish in accordance with the following prescribed conditions:

(a) It is used or intended for use alone as a preservative and color fixative in canned pet food containing fish, meat, and fish and meat byproducts so that the level of sodium nitrite does not exceed 20 parts per million.

(b) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (a) of this section.

§ 573.720 Petrolatum.

Petrolatum may be safely used in or on animal feed, subject to the following prescribed conditions:

(a) Petrolatum complies with the specifications set forth in the U.S. Pharmacopeia XVI for white petrolatum or in The National Formulary XII for yellow petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 121.1156(b) of this chapter.

Ultraviolet absorbance per centimeter path length:

Millimicrons:	Maximum
280-289	0.25
290-299	.20
300-359	.14
360-400	.04

(c) It is used in animal feed for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks, and to improve resistance to moisture of such pellets, cubes, or blocks.

(d) The quantity of petrolatum present in animal feeds from the uses specified in paragraph (c) of this section shall not exceed 3 percent in mineral supplements nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

(e) When used in combination with technical white mineral oil for the uses described in paragraph (c) of this section, the total quantity of combined petrolatum and technical white mineral oil shall not exceed the limits prescribed in paragraph (d) of this section.

(f) Petrolatum may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

§ 573.740 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons complying with § 121.1182 (a) and (b) of this chapter may be safely used in an amount not in excess of that required as a component of insecticide formulations used in compliance with regulations issued in this part.

§ 573.760 Poloxalene.

The food additive poloxalene may be safely used in accordance with the following prescribed conditions:

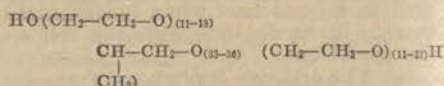
(a) The additive consists of polyoxypropylene-polyoxyethylene glycol non-ionic block polymer meeting the following specifications:

(1) Molecular weight range: 2,850-3,150.

(2) Hydroxyl number: 35.7-39.4.

(3) Cloud point (10 percent solution): 42° C-46° C.

(4) Structural formula:



(b) In feed as a surfactant for the flaking of feed grains when added to liquid grain conditioner in an amount not to exceed 1.0 percent of the conditioner. The conditioner is added to the feed at a rate of 1 quart per ton of feed.

(c) The label and labeling shall bear, in addition to the other information required by the act:

(1) The name of the additive.

(2) Adequate directions and warnings for use.

§ 573.780 Polyethylene.

(a) *Identity.* Polyethylene consists of basic polymers manufactured by the catalytic polymerization of ethylene.

(b) *Specifications.* (1) For the purposes of this section, polyethylene shall meet the specifications in item 2.1 of § 121.2501 (c) of this chapter.

(2) The polyethylene is designed in a pellet form in a configuration presenting maximum angular surface having the following dimensions in centimeters:

$$0.9 \pm 0.1 \times 0.8 \pm 0.1 \times 1.2 \pm 0.1$$

(c) *Use.* It is used as a replacement for roughage in feedlot rations for finishing slaughter cattle.

(d) *Labeling.* The labels and labeling shall bear in addition to the other information required by the act:

(1) The name of the additive "polyethylene roughage replacement."

(2) Adequate directions for use which shall provide for the administration of one-half pound of polyethylene pellets per head per day for 6 successive days. All natural roughage should be removed for a minimum of 12 hours prior to administration of polyethylene roughage replacement. Roughage replacement must be adequately mixed in the ration for uniform distribution.

§ 573.800 Polyethylene glycol (400) mono- and diolate.

(a) The food additive polyethylene glycol (400) mono- and diolate meets the following specifications: Saponification number, 80-88; acid number, 5.0 maximum; and average molecular weight range, 640-680.

(b) It is used as a processing aid in the production of animal feeds when present as a result of its addition to molasses in an amount not to exceed 250 parts per million of the molasses.

§ 573.820 Polyoxyethylene glycol (400) mono- and diolates.

The food additive polyoxyethylene glycol (400) mono- and diolates may be

safely used as an emulsifier in calf-milk replacer formulations.

§ 573.840 Polysorbate 60.

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) It is used alone or in combination with sorbitan monostearate as an emulsifier in mineral premixes and dietary supplements for animal feeds.

(b) It is used as an emulsifier in milk-replacer formulations for calves.

§ 573.860 Polysorbate 80.

The food additive polysorbate 80 (polyoxyethylene (20) sorbitan monooleate) may be safely used as an emulsifier in milk-replacer formulations for calves.

§ 573.880 Normal propyl alcohol.

Normal propyl alcohol may be safely used in feeds and feed supplements for cattle as a source of metabolizable energy. It is incorporated in the feed or feed supplement in an amount which provides not more than 54.5 grams of the additive per head per day.

§ 573.900 Pyrophyllite.

Pyrophyllite (aluminum silicate monohydrate) may be safely used as the sole anticaking aid, blending agent, pelleting aid, or carrier in animal feed when incorporated therein in an amount not to exceed 2 percent in complete animal feed.

§ 573.920 Selenium.

The food additive selenium may be safely used in accordance with the following prescribed conditions:

(a) The additive is used in animal feed as a nutrient in the form of sodium selenite or sodium selenate.

(b) It is added to the complete feed of growing chickens up to 16 weeks of age and to the complete feed of swine at a level not to exceed 0.1 part per million of added selenium; it is added to the complete feed of turkeys at a level not to exceed 0.2 part per million of added selenium.

(c) The additive shall be incorporated into each ton of the complete feed of growing chickens up to 16 weeks of age and of swine by a premix containing no more than 90.8 milligrams of added selenium and weighing not less than 1 pound. The additive shall be incorporated into each ton of the complete feed of turkeys by a premix containing no more than 181.6 milligrams of added selenium and weighing not less than 2 pounds.

(d) The premix manufacturer shall analyze each production batch of selenium premix and shall establish by such analysis that the levels of selenium specified in paragraph (c) of this section are not exceeded.

(e) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: "Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted."

(f) Feeds containing added selenium may not be administered to hens laying eggs for human consumption.

§ 573.940 Silicon dioxide.

The food additive silicon dioxide may be safely used in animal feed in accordance with the following conditions:

(a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

(b) It is used or intended for use in feed components as an anticaking agent, and/or grinding aid, as follows:

Feed component:	Limitations (percent)
BHT (butylated hydroxytoluene)	2
Methionine hydroxy analog and its calcium salts	1
Piperazine, piperazine salts	0.8
Sodium propionate	1
Urea	1
Vitamins	3

(c) It is used in feed as an anticaking agent in an amount not to exceed that reasonably required to accomplish its intended effect and in no case in an amount to exceed 2 percent by weight of the finished feed.

§ 573.960 Sorbitan monostearate.

The food additive sorbitan monostearate may be safely used alone or in combination with polysorbate 60 as an emulsifier in mineral premixes and dietary supplements for animal feeds.

§ 573.980 Taurine.

The food additive taurine (2-aminoethanesulfonic acid) may be safely used in feed in accordance with the following prescribed conditions:

(a) It is used as a nutritional supplement in the feed of growing chickens.

(b) It is added to complete feeds so that the total taurine content does not exceed 0.054 percent of the feed.

(c) To assure safe use of the additive, the label and labeling shall bear in addition to the other information required by the act:

- (1) The name of the additive.
- (2) The quantity of the additive contained therein.
- (3) Adequate directions for use.

§ 573.1000 Verxite.

The food additive verxite may be safely used in animal feed in accordance with the following prescribed conditions:

(a) The additive is a magnesium-aluminum-iron silicate conforming to one of the following:

(1) (i) Verxite granules: The additive contains a minimum of 98 percent of hydrobiotite; it is thermally expanded and has a bulk density of from 5 to 9 pounds per cubic foot.

(ii) It is used or intended for use: (a) In poultry feed at a level not to exceed 5 percent of the weight of the finished feed as a nonnutritive bulking agent for restricting calorie intake in pullet replacement feeds.

(b) As an anticaking or blending agent, pelleting aid, or nonnutritive car-

rier for the incorporation of nutrients in poultry, swine, dog, or ruminant feeds, in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1.5 percent of the dog feed or 5 percent of the final feed for other animals.

(2) (i) Verxite flakes: The additive contains a minimum of 98 percent of hydrobiotite; it has a bulk density of from 20 to 30 pounds per cubic foot.

(ii) It is used or intended for use as an anticaking or blending agent in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1 percent by weight of the final feed for ruminants.

(3) (i) Verxite grits: The additive contains a minimum of 80 percent of hydrobiotite; it has a bulk density of from 40 to 50 pounds per cubic foot.

(ii) It is used or intended for use as a partial roughage replacement in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1 percent by weight of the final feed.

(b) To assure safe use of the additive, the label of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear, in addition to the other information required by the act, the name of the additive (verxite granules, verxite flakes, or verxite grits), adequate directions for use, and, when the additive is present in excess of 1 percent, a statement of the quantity of the additive contained therein and the term "nonnutritive" in juxtaposition therewith.

§ 573.1020 Yellow prussiate of soda.

Yellow prussiate of soda (sodium ferrocyanide decahydrate; $\text{Na}_4\text{Fe}(\text{CN})_6 \cdot 10\text{H}_2\text{O}$) may be safely used as an anticaking agent in salt for animal consumption at a level not to exceed 13 parts per million. The additive contains a minimum of 99.0 percent by weight of sodium ferrocyanide decahydrate.

PART 582—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions	
Sec.	
582.1	Substances that are generally recognized as safe.
582.10	Spices and other natural seasonings and flavorings.
582.20	Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).
582.30	Natural substances used in conjunction with spices and other natural seasonings and flavorings.
582.40	Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.
582.50	Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.
582.60	Synthetic flavoring substances and adjuvants.
582.80	Trace minerals added to animal foods.
582.99	Adjuvants for pesticide chemicals.

Subpart B—General Purpose Food Additives

Sec.	
582.1005	Acetic acid.
582.1009	Adipic acid.
582.1033	Citric acid.
582.1057	Hydrochloric acid.
582.1061	Lactic acid.
582.1069	Malic acid.
582.1073	Phosphoric acid.
582.1077	Potassium acid tartrate.
582.1087	Sodium acid pyrophosphate.
582.1091	Succinic acid.
582.1095	Sulfuric acid.
582.1099	Tartaric acid.
582.1125	Aluminum sulfate.
582.1127	Aluminum ammonium sulfate.
582.1129	Aluminum potassium sulfate.
582.1131	Aluminum sodium sulfate.
582.1135	Ammonium bicarbonate.
582.1137	Ammonium carbonate.
582.1139	Ammonium hydroxide.
582.1141	Ammonium phosphate.
582.1143	Ammonium sulfate.
582.1155	Bentonite.
582.1165	Butane.
582.1191	Calcium carbonate.
582.1193	Calcium chloride.
582.1195	Calcium citrate.
582.1199	Calcium gluconate.
582.1205	Calcium hydroxide.
582.1207	Calcium lactate.
582.1210	Calcium oxide.
582.1217	Calcium phosphate.
582.1235	Caramel.
582.1240	Carbon dioxide.
582.1275	Dextrins.
582.1320	Glycerin.
582.1324	Glycerol monostearate.
582.1355	Helium.
582.1366	Hydrogen peroxide.
582.1400	Lecithin.
582.1425	Magnesium carbonate.
582.1428	Magnesium hydroxide.
582.1431	Magnesium oxide.
582.1480	Methylcellulose.
582.1500	Monoammonium glutamate.
582.1516	Monopotassium glutamate.
582.1540	Nitrogen.
582.1585	Papain.
582.1613	Potassium bicarbonate.
582.1619	Potassium carbonate.
582.1625	Potassium citrate.
582.1631	Potassium hydroxide.
582.1643	Potassium sulfate.
582.1656	Propane.
582.1666	Propylene glycol.
582.1685	Rennet.
582.1711	Silica aerogel.
582.1721	Sodium acetate.
582.1736	Sodium bicarbonate.
582.1742	Sodium carbonate.
582.1745	Sodium carboxymethylcellulose.
582.1748	Sodium caseinate.
582.1751	Sodium citrate.
582.1763	Sodium hydroxide.
582.1775	Sodium pectinate.
582.1778	Sodium phosphate.
582.1781	Sodium aluminum phosphate.
582.1792	Sodium sesquicarbonate.
582.1804	Sodium potassium tartrate.
582.1810	Sodium tripolyphosphate.
582.1901	Triacetin.
582.1973	Beeswax.
582.1975	Bleached beeswax.
582.1978	Carnauba wax.

Subpart C—Anticaking Agents

582.2122	Aluminum calcium silicate.
582.2227	Calcium silicate.
582.2437	Magnesium silicate.
582.2727	Sodium aluminosilicate.
582.2729	Hydrated sodium calcium aluminosilicate.
582.2906	Tricalcium silicate.

Subpart D—Chemical Preservatives

Sec.	
582.3013	Ascorbic acid.
582.3021	Benzoic acid.
582.3041	Erythorbic acid.
582.3081	Propionic acid.
582.3089	Sorbic acid.
582.3109	Thiodipropionic acid.
582.3149	Ascorbyl palmitate.
582.3169	Butylated hydroxyanisole.
582.3173	Butylated hydroxytoluene.
582.3189	Calcium ascorbate.
582.3221	Calcium propionate.
582.3225	Calcium sorbate.
582.3280	Dilauryl thiodipropionate.
582.3336	Gum gualac.
582.3490	Methylparaben.
582.3616	Potassium bisulfite.
582.3637	Potassium metabisulfite.
582.3640	Potassium sorbate.
582.3660	Propyl gallate.
582.3670	Propylparaben.
582.3731	Sodium ascorbate.
582.3733	Sodium benzoate.
582.3739	Sodium bisulfite.
582.3766	Sodium metabisulfite.
582.3784	Sodium propionate.
582.3795	Sodium sorbate.
582.3798	Sodium sulfite.
582.3845	Stannous chloride.
582.3862	Sulfur dioxide.
582.3890	Tocopherols.

Subpart E—Emulsifying Agents

582.4101	Diacyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
582.4505	Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.
582.4521	Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
582.4666	Propylene glycol

Subpart F—Nutrients and/or Dietary Supplements

582.5013	Ascorbic acid.
582.5017	Aspartic acid.
582.5049	Aminoacetic acid.
582.5065	Linoleic acid.
582.5118	Alanine.
582.5145	Arginine.
582.5159	Biotin.
582.5191	Calcium carbonate.
582.5195	Calcium citrate.
582.5201	Calcium glycerophosphate.
582.5210	Calcium oxide.
582.5212	Calcium pantothenate.
582.5217	Calcium phosphate.
582.5223	Calcium pyrophosphate.
582.5230	Calcium sulfate.
582.5245	Carotene.
582.5250	Choline bitartrate.
582.5252	Choline chloride.
582.5260	Copper gluconate.
582.5271	Cysteine.
582.5273	Cystine.
582.5301	Ferric phosphate.
582.5304	Ferric pyrophosphate.
582.5306	Ferric sodium pyrophosphate.
582.5308	Ferrous gluconate.
582.5311	Ferrous lactate.
582.5315	Ferrous sulfate.
582.5361	Histidine.
582.5370	Inositol.
582.5375	Iron reduced.
582.5381	Isoleucine.
582.5406	Leucine.
582.5411	Lysine.
582.5431	Magnesium oxide.
582.5434	Magnesium phosphate.
582.5443	Magnesium sulfate.

Sec.	
582.5446	Manganese chloride.
582.5449	Manganese citrate.
582.5452	Manganese gluconate.
582.5455	Manganese glycerophosphate.
582.5458	Manganese hypophosphite.
582.5461	Manganese sulfate.
582.5464	Manganous oxide.
582.5470	Mannitol.
582.5475	Methionine.
582.5477	Methionine hydroxy analog and its calcium salts.
582.5530	Niacin.
582.5535	Niacinamide.
582.5580	D-Pantothenyl alcohol.
582.5590	Phenylalanine.
582.5622	Potassium chloride.
582.5628	Potassium glycerophosphate.
582.5634	Potassium iodide.
582.5650	Proline.
582.5676	Pyridoxine hydrochloride.
582.5695	Riboflavin.
582.5697	Riboflavin-5-phosphate.
582.5701	Serine.
582.5772	Sodium pantothenate.
582.5778	Sodium phosphate.
582.5835	Sorbitol.
582.5875	Thiamine hydrochloride.
582.5878	Thiamine mononitrate.
582.5881	Threonine.
582.5890	Tocopherols.
582.5892	α -Tocopherol acetate.
582.5915	Tryptophane.
582.5920	Tyrosine.
582.5925	Valine.
582.5930	Vitamin A.
582.5933	Vitamin A acetate.
582.5936	Vitamin A palmitate.
582.5945	Vitamin B ₁₂ .
582.5950	Vitamin D ₂ .
582.5953	Vitamin D ₃ .
582.5985	Zinc chloride.
582.5988	Zinc gluconate.
582.5991	Zinc oxide.
582.5994	Zinc stearate.
582.5997	Zinc sulfate.

Subpart G—Sequestrants

582.6033	Citric acid.
582.6085	Sodium acid phosphate.
582.6099	Tartaric acid.
582.6185	Calcium acetate.
582.6193	Calcium chloride.
582.6195	Calcium citrate.
582.6197	Calcium diacetate.
582.6199	Calcium gluconate.
582.6203	Calcium hexametaphosphate.
582.6215	Monobasic calcium phosphate.
582.6219	Calcium phytate.
582.6285	Dipotassium phosphate.
582.6290	Disodium phosphate.
582.6386	Isopropyl citrate.
582.6511	Monoisopropyl citrate.
582.6540	Potassium citrate.
582.6651	Sodium citrate.
582.6754	Sodium diacetate.
582.6757	Sodium gluconate.
582.6760	Sodium hexametaphosphate.
582.6769	Sodium metaphosphate.
582.6778	Sodium phosphate.
582.6787	Sodium pyrophosphate.
582.6789	Tetra sodium pyrophosphate.
582.6801	Sodium tartrate.
582.6804	Sodium potassium tartrate.
582.6807	Sodium thiosulfate.
582.6810	Sodium tripolyphosphate.
582.6851	Stearyl citrate.

Subpart H—Stabilizers

582.7115	Agar-agar.
582.7133	Ammonium alginate.
582.7187	Calcium alginate.
582.7255	Chondrus extract.
582.7330	Gum arabic.
582.7333	Gum ghatti.

Sec.	
582.7339	Guar gum.
582.7343	Locust bean gum.
582.7349	Sterculia gum.
582.7351	Gum tragacanth.
582.7610	Potassium alginate.
582.7724	Sodium alginate.

AUTHORITY: Secs. 201(s), 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 582.1 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use. The lists in Subparts B through H of this part include additional substances that, when used for the purposes indicated, in accordance with good manufacturing or feeding practice, are regarded by the Commissioner as generally recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing or feeding practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to animal food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of animal food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for animals.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are listed in Subparts B through H of this part. When the status of a substance has been reevaluated and affirmed as GRAS or deleted from Subparts B through H of this part, an appropriate explanation will be noted, e.g., "affirmed as GRAS," "food additive regulation," "interim food additive regulation," or "prohibited from use in food," with a reference to the appropriate new regula-

tion. Such notation will apply only to the specific use covered by the review, e.g., direct animal food use and/or indirect animal food use and/or animal feed use and will not affect its status for other uses not specified in the referenced regulation, pending a specific review of such other uses.

§ 582.10 Spices and other natural seasonings and flavorings.

Spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Botanical name of plant source
Alfalfa herb and seed	<i>Medicago sativa</i> L.
Allspice	<i>Pimenta officinalis</i> Lindl.
Ambrette seed	<i>Hibiscus abelmoschus</i> L.
Angelica	<i>Angelica archangelica</i> L. or other spp. of <i>Angelica</i> .
Angelica root	Do.
Angelica seed	Do.
Angostura (cusparia bark)	<i>Galipea officinalis</i> Hancock.
Anise	<i>Pimpinella anisum</i> L.
Anise, star	<i>Illicium verum</i> Hook. f.
Balm (lemon balm)	<i>Melissa officinalis</i> L.
Basil, bush	<i>Ocimum minimum</i> L.
Basil, sweet	<i>Ocimum basilicum</i> L.
Bay	<i>Laurus nobilis</i> L.
Calendula	<i>Calendula officinalis</i> L.
Camomile (chamomile), English or Roman.	<i>Anthemis nobilis</i> L.
Camomile (chamomile), German or Hungarian.	<i>Matricaria chamomilla</i> L.
Capers	<i>Capparis spinosa</i> L.
Capsicum	<i>Capsicum frutescens</i> L. or <i>Capsicum annuum</i> L.
Caraway	<i>Carum carvi</i> L.
Caraway, black (black cumlin)	<i>Nigella sativa</i> L.
Cardamom (cardamon)	<i>Elettaria cardamomum</i> Maton.
Cassia, Chinese	<i>Cinnamomum cassia</i> Blume.
Cassia, Padang or Batavia	<i>Cinnamomum burmanni</i> Blume.
Cassia, Saigon	<i>Cinnamomum loureirii</i> Nees.
Cayenne pepper	<i>Capsicum frutescens</i> L. or <i>Capsicum annuum</i> L.
Celery seed	<i>Apium graveolens</i> L.
Chervil	<i>Anthriscus cerefolium</i> (L.) Hoffm.
Chives	<i>Allium schoenoprasum</i> L.
Cinnamon, Ceylon	<i>Cinnamomum zeylanicum</i> Nees.
Cinnamon, Chinese	<i>Cinnamomum cassia</i> Blume.
Cinnamon, Saigon	<i>Cinnamomum loureirii</i> Nees.
Clary (clary sage)	<i>Salvia sclarea</i> L.
Clover	<i>Trifolium</i> spp.
Cloves	<i>Eugenia caryophyllata</i> Thunb.
Coriander	<i>Coriandrum sativum</i> L.
Cumin (cummin)	<i>Cuminum cyminum</i> L.
Cumin, black (black caraway)	<i>Nigella sativa</i> L.
Dill	<i>Anethum graveolens</i> L.
Elder flowers	<i>Sambucus canadensis</i> L.
Fennel, common	<i>Foeniculum vulgare</i> Mill.
Fennel, sweet (finocchio, Florence fennel).	<i>Foeniculum vulgare</i> Mill. var. dulce (DC.) Alex.
Fenugreek	<i>Trigonella foenum-graecum</i> L.
Galanga (galangal)	<i>Alpinia officinarum</i> Hance.
Garlic	<i>Allium sativum</i> L.
Geranium	<i>Pelargonium</i> spp.
Ginger	<i>Zingiber officinale</i> Rosc.
Glycyrrhiza	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Grains of paradise	<i>Amomum melegueta</i> Rosc.
Horehound (hoarhound)	<i>Marrubium vulgare</i> L.
Horseradish	<i>Armoracia lapathifolia</i> Gillb.
Hyssop	<i>Hyssopus officinalis</i> L.
Lavender	<i>Lavandula officinalis</i> Chaix.
Licorice	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Linden flowers	<i>Tilia</i> spp.
Mace	<i>Myristica fragrans</i> Houtt.
Marigold, pot.	<i>Calendula officinalis</i> L.
Marjoram, pot.	<i>Majorana onites</i> (L.) Benth.
Marjoram, sweet	<i>Majorana hortensis</i> Moench.
Mustard, black or brown	<i>Brassica nigra</i> (L.) Koch.
Mustard, brown	<i>Brassica juncea</i> (L.) Coss.
Mustard, white or yellow	<i>Brassica hirta</i> Moench.
Nutmeg	<i>Myristica fragrans</i> Houtt.
Oregano (oreganum, Mexican oregano, Mexican sage, origan).	<i>Lippia</i> spp.

Common name	Botanical name of plant source
Paprika	<i>Capsicum annuum</i> L.
Parsley	<i>Petroselinum crispum</i> (Mill.) Mansf.
Pepper, black	<i>Piper nigrum</i> L.
Pepper, cayenne	<i>Capsicum frutescens</i> L. or <i>Capsicum annuum</i> L.
Pepper, red	Do.
Pepper, white	<i>Piper nigrum</i> L.
Peppermint	<i>Mentha piperita</i> L.
Poppy seed	<i>Papaver somniferum</i> L.
Pot marigold	<i>Calendula officinalis</i> L.
Pot marjoram	<i>Majorana onites</i> (L.) Benth.
Rosemary	<i>Rosmarinus officinalis</i> L.
Rue	<i>Ruta graveolens</i> L.
Saffron	<i>Crocus sativus</i> L.
Sage	<i>Salvia officinalis</i> L.
Sage, Greek	<i>Salvia triloba</i> L.
Savory, summer	<i>Satureia hortensis</i> L. (Satureja).
Savory, winter	<i>Satureia montana</i> L. (Satureja).
Sesame	<i>Sesamum indicum</i> L.
Spearmint	<i>Mentha spicata</i> L.
Star anise	<i>Illicium verum</i> Hook. f.
Tarragon	<i>Artemisia dracunculoides</i> L.
Thyme	<i>Thymus vulgaris</i> L.
Thyme, wild or creeping	<i>Thymus serpyllum</i> L.
Turmeric	<i>Curcuma longa</i> L.
Vanilla	<i>Vanilla planifolia</i> Andr. or <i>Vanilla tahitensis</i> J. W. Moore
Zedoary	<i>Curcuma zedoaria</i> Rose.

§ 582.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).

Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Botanical name of plant source
Alfalfa	<i>Medicago sativa</i> L.
Allspice	<i>Pimenta officinalis</i> Lindl.
Almond, bitter (free from prussic acid)	<i>Prunus amygdalus</i> Batsch, <i>Prunus armeniaca</i> L., or <i>Prunus persica</i> (L.) Batsch.
Ambrette (seed)	<i>Hibiscus moschatus</i> Moench.
Angelica root	<i>Angelica archangelica</i> L.
Angelica seed	Do.
Angelica stem	Do.
Angostura (cuscuta bark)	<i>Galipea officinalis</i> Hancock.
Anise	<i>Pimpinella anisum</i> L.
Asafetida	<i>Ferula assa-foetida</i> L. and related spp. of <i>Ferula</i> .
Balm (lemon balm)	<i>Melissa officinalis</i> L.
Balsam of Peru	<i>Myroxylon pereirae</i> Klotzsch.
Basil	<i>Ocimum basilicum</i> L.
Bay leaves	<i>Laurus nobilis</i> L.
Bay (myrcia oil)	<i>Pimenta racemosa</i> (Mill.) J. W. Moore.
Bergamot (bergamot orange)	<i>Citrus aurantium</i> L. subsp. <i>bergamia</i> Wright et Arn.
Bitter almond (free from prussic acid)	<i>Prunus amygdalus</i> Batsch, <i>Prunus armeniaca</i> L., or <i>Prunus persica</i> (L.) Batsch.
Bois de rose	<i>Aniba rosaeodora</i> Ducke.
Cacao	<i>Theobroma cacao</i> L.
Camomile (chamomile) flowers, Hungarian	<i>Matricaria chamomilla</i> L.
Camomile (chamomile) flowers, Roman or English	<i>Anthemis nobilis</i> L.
Cananga	<i>Cananga odorata</i> Hook. f. and Thoms.
Capsicum	<i>Capsicum frutescens</i> L. and <i>Capsicum annuum</i> L.
Caraway	<i>Carum carvi</i> L.
Cardamom seed (cardamon)	<i>Elettaria cardamomum</i> Maton.
Carob bean	<i>Ceratonia siliqua</i> L.
Carrot	<i>Daucus carota</i> L.
Cascarilla bark	<i>Croton eluteria</i> Benn.
Cassia bark, Chinese	<i>Cinnamomum cassia</i> Blume.
Cassia bark, Padang or Batavia	<i>Cinnamomum burmanni</i> Blume.
Cassia bark, Saigon	<i>Cinnamomum loureirii</i> Nees.
Celery seed	<i>Apium graveolens</i> L.
Cherry, wild, bark	<i>Prunus serotina</i> Ehrh.
Chervil	<i>Anthriscus cerefolium</i> (L.) Hoffm.
Chicory	<i>Cichorium intybus</i> L.
Cinnamon bark, Ceylon	<i>Cinnamomum zeylanicum</i> Nees.
Cinnamon bark, Chinese	<i>Cinnamomum cassia</i> Blume.
Cinnamon bark, Saigon	<i>Cinnamomum loureirii</i> Nees.
Cinnamon leaf, Ceylon	<i>Cinnamomum zeylanicum</i> Nees.
Cinnamon leaf, Chinese	<i>Cinnamomum cassia</i> Blume.
Cinnamon leaf, Saigon	<i>Cinnamomum loureirii</i> Nees.

Common name	Botanical name of plant source
Citronella	<i>Cymbopogon nardus</i> Rendle.
Citrus peels	<i>Citrus</i> spp.
Clary (clary sage)	<i>Salvia sclarea</i> L.
Clove bud	<i>Eugenia caryophyllata</i> Thunb.
Clove leaf	Do.
Clove stem	Do.
Clover	<i>Trifolium</i> spp.
Coca (decocalnized)	<i>Erythroxylum coca</i> Lam. and other spp. of <i>Erythroxylum</i> .
Coffee	<i>Coffea</i> spp.
Cola nut	<i>Cola acuminata</i> Schott and Endl., and other spp. of <i>Cola</i> .
Coriander	<i>Coriandrum sativum</i> L.
Corn silk	<i>Zea mays</i> L.
Cumin (cummin)	<i>Cuminum cyminum</i> L.
Curacao orange peel (orange, bitter peel).	<i>Citrus aurantium</i> L.
Cusparia bark	<i>Galipea officinalis</i> Hancock.
Dandelion	<i>Taraxacum officinale</i> Weber and <i>T. laevigatum</i> DC.
Dandelion root	Do.
Dill	<i>Anethum graveolens</i> L.
Dog grass (quackgrass, triticum)	<i>Agropyron repens</i> (L.) Beauv.
Elder flowers	<i>Sambucus canadensis</i> L. and <i>S. nigra</i> L.
Estragole (esdragol, esdragon, taragon).	<i>Artemisia dracunculus</i> L.
Estragon (tarragon)	Do.
Fennel, sweet	<i>Foeniculum vulgare</i> Mill.
Fenugreek	<i>Trigonella foenum-graecum</i> L.
Galanga (galangal)	<i>Alpinia officinarum</i> Hance.
Garlic	<i>Allium sativum</i> L.
Geranium	<i>Pelargonium</i> spp.
Geranium, East Indian	<i>Cymbopogon martini</i> Stapf.
Geranium, rose	<i>Pelargonium graveolens</i> L'Her.
Ginger	<i>Zingiber officinale</i> Rosc.
Glycyrrhiza	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Glycyrrhizin, ammoniated	Do.
Grapefruit	<i>Citrus paradisi</i> Macf.
Guava	<i>Psidium</i> spp.
Hickory bark	<i>Carya</i> spp.
Horehound (hoarhound)	<i>Marrubium vulgare</i> L.
Hops	<i>Humulus lupulus</i> L.
Horsemint	<i>Monarda punctata</i> L.
Hyssop	<i>Hyssopus officinalis</i> L.
Immortelle	<i>Helichrysum augustifolium</i> DC.
Jasmine	<i>Jasminum officinale</i> L. and other spp. of <i>Jasminum</i> .
Juniper (berries)	<i>Juniperus communis</i> L.
Kola nut	<i>Cola acuminata</i> Schott and Endl., and other spp. of <i>Cola</i> .
Laurel berries	<i>Laurus nobilis</i> L.
Laurel leaves	<i>Laurus</i> spp.
Lavender	<i>Lavandula officinalis</i> Chaix.
Lavender, spike	<i>Lavandula latifolia</i> Vill.
Lavandin	Hybrids between <i>Lavandula officinalis</i> Chaix and <i>Lavandula latifolia</i> Vill.
Lemon	<i>Citrus limon</i> (L.) Burm. f.
Lemon balm (see balm).	
Lemon grass	<i>Cymbopogon citratus</i> DC. and <i>Cymbopogon flexuosus</i> Stapf.
Lemon peel	<i>Citrus limon</i> (L.) Burm. f.
Licorice	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Lime	<i>Citrus aurantifolia</i> Swingle.
Linden flowers	<i>Tilia</i> spp.
Locust bean	<i>Ceratonia siliqua</i> L.
Lupulin	<i>Humulus lupulus</i> L.
Mace	<i>Myristica fragrans</i> Houtt.
Malt (extract)	<i>Hordeum vulgare</i> L., or other grains.
Mandarin	<i>Citrus reticulata</i> Blanco.
Marjoram, sweet	<i>Majorana hortensis</i> Moench.
Maté	<i>Ilex paraguariensis</i> St. Hil.
Melissa (see balm).	
Menthol	<i>Mentha</i> spp.
Menthyl acetate	Do.
Molasses (extract)	<i>Saccharum officinarum</i> L.
Mustard	<i>Brassica</i> spp.
Naringin	<i>Citrus paradisi</i> Macf.
Neroli, bigarade	<i>Citrus aurantium</i> L.

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Common name	Botanical name of plant source
Nutmeg	<i>Myristica fragrans</i> Houtt.
Onion	<i>Allium cepa</i> L.
Orange, bitter, flowers	<i>Citrus aurantium</i> L.
Orange, bitter, peel	Do.
Orange leaf	<i>Citrus sinensis</i> (L.) Osbeck.
Orange, sweet	Do.
Orange, sweet, flowers	Do.
Orange, sweet, peel	Do.
Origanum	<i>Origanum</i> spp.
Palmarosa	<i>Cymbopogon martini</i> Stapf.
Paprika	<i>Capsicum annuum</i> L.
Parsley	<i>Petroselinum crispum</i> (Mill.) Mansf.
Pepper, black	<i>Piper nigrum</i> L.
Pepper, white	Do.
Peppermint	<i>Mentha piperita</i> L.
Peruvian balsam	<i>Myrcylon pereirae</i> Klotzsch.
Petitgrain	<i>Citrus aurantium</i> L.
Petitgrain lemon	<i>Citrus limon</i> (L.) Burm. f.
Petitgrain mandarin or tangerine	<i>Citrus reticulata</i> Blanco.
Pimenta	<i>Pimenta officinalis</i> Lindl.
Pimenta leaf	<i>Pimenta officinalis</i> Lindl.
Pipsissewa leaves	<i>Chimaphila umbellata</i> Nutt.
Pomegranate	<i>Punica granatum</i> L.
Prickly ash bark	<i>Xanthoxylum</i> (or <i>Zanthoxylum</i>) <i>Americanum</i> Mill. or <i>Xanthoxylum clava-herculis</i> L.
Rose absolute	<i>Rosa alba</i> L., <i>Rosa centifolia</i> L., <i>Rosa damascena</i> Mill., <i>Rosa gallica</i> L., and vars. of these spp.
Rose (otto of roses, attar of roses)	Do.
Rose buds	Do.
Rose flowers	Do.
Rose fruit (hips)	Do.
Rose geranium	<i>Pelargonium graveolens</i> L'Her.
Rose leaves	<i>Rosa</i> spp.
Rosemary	<i>Rosmarinus officinalis</i> L.
Rue	<i>Ruta graveolens</i> L.
Saffron	<i>Crocus sativus</i> L.
Sage	<i>Salvia officinalis</i> L.
Sage, Greek	<i>Salvia triloba</i> L.
Sage, Spanish	<i>Salvia lavandulaefolia</i> Vahl.
St. John's bread	<i>Cerantia siliqua</i> L.
Savory, summer	<i>Satureia hortensis</i> L.
Savory, winter	<i>Satureia montana</i> L.
Schinus molle	<i>Schinus molle</i> L.
Sloe berries (blackthorn berries)	<i>Prunus spinosa</i> L.
Spearmint	<i>Mentha spicata</i> L.
Spike lavender	<i>Lavandula latifolia</i> Vill.
Tamarind	<i>Tamarindus indica</i> L.
Tangerine	<i>Citrus reticulata</i> Blanco.
Tannic acid	Nutgalls of <i>Quercus infectoria</i> Oliver and related spp. of <i>Quercus</i> . Also in many other plants.
Tarragon	<i>Artemisia dracunculoides</i> L.
Tea	<i>Thea sinensis</i> L.
Thyme	<i>Thymus vulgaris</i> L. and <i>Thymus zygis</i> var. <i>gracilis</i> Boiss.
Thyme, white	Do.
Thyme, wild or creeping	<i>Thymus serpyllum</i> L.
Triticum (see dog grass).	
Tuberose	<i>Polianthes tuberosa</i> L.
Turmeric	<i>Curcuma longa</i> L.
Vanilla	<i>Vanilla planifolia</i> Andr. or <i>Vanilla tahitensis</i> J. W. Moore.
Violet flowers	<i>Viola odorata</i> L.
Violet leaves	Do.
Violet leaves absolute	Do.
Wild cherry bark	<i>Prunus serotina</i> Ehrh.
Ylang-ylang	<i>Cananga odorata</i> Hook. f. and Thoms.
Zedoary bark	<i>Curcuma zedoaria</i> Rose.

§ 582.30 Natural substances used in conjunction with spices and other natural seasonings and flavorings.

Natural substances used in conjunction with spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Botanical name of plant source
Algae, brown (kelp)	<i>Laminaria</i> spp. and <i>Nereocystis</i> spp.
Algae, red	<i>Porphyra</i> spp. and <i>Rhodomenia palmata</i> (L.) Grev.
Dulse	<i>Rhodomenia palmata</i> (L.)

§ 582.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.

Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Botanical name of plant source
Algae, brown	<i>Laminaria</i> spp. and <i>Nereocystis</i> spp.
Algae, red	<i>Porphyra</i> spp. and <i>Rhododymenia palmata</i> (L.) Grev.
Apricot kernel (persic oil)	<i>Prunus armeniaca</i> L.
Dulse	<i>Rhododymenia palmata</i> (L.) Grev.
Kelp (see algae, brown)	
Peach kernel (persic oil)	<i>Prunus persica</i> Sieb. et Zucc.
Peanut stearine	<i>Arachis hypogaea</i> L.
Persic oil (see apricot kernel and peach kernel)	
Quince seed	<i>Cydonia oblonga</i> Miller.

§ 582.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.

Certain other spices, seasonings, essential oils, oleoresins, and natural extracts that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Derivation
Ambergris	<i>Physeter macrocephalus</i> L.
Castoreum	Castor fiber L. and <i>C. canadensis</i> Kuhl.
Civet (zibeth, zibet, zibetum)	Civet cats, <i>Viverra civetta</i> Schreber and <i>Viverra zibetha</i> Schreber.
Cognac oil, white and green	<i>Ethyl oenanthe</i> , so-called.
Musk (Tonquin musk)	Musk deer, <i>Moschus moschiferus</i> L.

§ 582.60 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Acetaldehyde (ethanal).
Acetoin (acetyl methylcarbinol).
Aconitic acid (equisetic acid, citridic acid, achillic acid).
Anethole (parapropenyl anisole).
Benzaldehyde (benzoic aldehyde).
N-Butyric acid (butanoic acid).
d- or l-Carvone (carvol).
Cinnamaldehyde (cinnamic aldehyde).
Citral (2,6-dimethyloctadien-2,6-di-8, geraniol, neral).
Decanal (N-decylaldehyde, capraldehyde, capric aldehyde, caprinaldehyde, aldehyde C-10).
Diacetyl (2,3-butanedione).
Ethyl acetate.
Ethyl butyrate.
3-Methyl-3-phenyl glycidic acid ethyl ester (ethyl-methyl-phenyl-glycidate, so-called strawberry aldehyde, C-16 aldehyde).
Ethyl vanillin.
Eugenol.
Geraniol (3,7-dimethyl-2,6 and 3,6-octadien-1-ol).
Geranyl acetate (geraniol acetate).
Glycerol (glyceryl) tributyrate (tributyryl, butyryl).
Limonene (d-, l-, and dl-).
Linalool (linalol, 3,7-dimethyl-1,6-octadien-3-ol).
Linalyl acetate (bergamol).
1-Malic acid.
Methyl anthranilate (methyl-2-aminobenzoate).
Piperonal (3,4-methylenedioxy-benzaldehyde, heliotropin).
Vanillin.

§ 582.80 Trace minerals added to animal feeds.

These substances added to animal feeds as nutritional dietary supplements are generally recognized as safe when added at levels consistent with good feeding practice.¹

Element	Source compounds
Cobalt	Cobalt acetate. Cobalt carbonate. Cobalt chloride. Cobalt oxide. Cobalt sulfate.
Copper	Copper carbonate. Copper chloride. Copper gluconate. Copper hydroxide. Copper orthophosphate. Copper oxide. Copper pyrophosphate. Copper sulfate. Calcium iodate. Calcium iodobehenate. Cuprous iodide. 3,5-Diiodosalicylic acid. Ethylenediamine dihydroiodide.
Iodine	Potassium iodate. Potassium iodide. Sodium iodate. Sodium iodide. Thymol iodide. Iron ammonium citrate. Iron carbonate. Iron chloride. Iron gluconate. Iron oxide. Iron phosphate. Iron pyrophosphate. Iron sulfate. Reduced iron.
Iron	

¹ All substances listed may be in anhydrous or hydrated form.

Element	Source compounds
Manganese	Manganese acetate. Manganese carbonate. Manganese citrate (soluble). Manganese chloride. Manganese gluconate. Manganese orthophosphate. Manganese phosphate (di-basic). Manganese sulfate. Manganese oxide.
Zinc	Zinc acetate. Zinc carbonate. Zinc chloride. Zinc oxide. Zinc sulfate.

§ 582.99 Adjuvants for pesticide chemicals.

Adjuvants, identified and used in accordance with 40 CFR 180.1001 (c) and (d), which are added to pesticide use dilutions by a grower or applicator prior to application to the raw agricultural commodity, are exempt from the requirement of tolerances under section 409 of the act.

(Sec. 409, 72 Stat. 1785; 21 U.S.C. 348)

Subpart B—General Purpose Food Additives

§ 582.1005 Acetic acid.

- (a) *Product.* Acetic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1009 Adipic acid.

- (a) *Product.* Adipic acid.
(b) *[Reserved]*
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a buffer and neutralizing agent in accordance with good manufacturing or feeding practice.

§ 582.1033 Citric acid.

- (a) *Product.* Citric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1057 Hydrochloric acid.

- (a) *Product.* Hydrochloric acid.
(b) *[Reserved]*
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a buffer and neutralizing agent in accordance with good manufacturing or feeding practice.

§ 582.1061 Lactic acid.

- (a) *Product.* Lactic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1069 Malic acid.

(a) *Product.* Malic acid.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1073 Phosphoric acid.

(a) *Product.* Phosphoric acid.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1077 Potassium acid tartrate.

(a) *Product.* Potassium acid tartrate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1087 Sodium acid pyrophosphate.

(a) *Product.* Sodium acid pyrophosphate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1091 Succinic acid.

(a) *Product.* Succinic acid.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1095 Sulfuric acid.

(a) *Product.* Sulfuric acid.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1099 Tartaric acid.

(a) *Product.* Tartaric acid.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1125 Aluminum sulfate.

(a) *Product.* Aluminum sulfate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1127 Aluminum ammonium sulfate.

(a) *Product.* Aluminum ammonium sulfate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1129 Aluminum potassium sulfate.

(a) *Product.* Aluminum potassium sulfate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1131 Aluminum sodium sulfate.

(a) *Product.* Aluminum sodium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1135 Ammonium bicarbonate.

(a) *Product.* Ammonium bicarbonate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1137 Ammonium carbonate.

(a) *Product.* Ammonium carbonate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1139 Ammonium hydroxide.

(a) *Product.* Ammonium hydroxide.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1141 Ammonium phosphate.

(a) *Product.* Ammonium phosphate (mono- and dibasic).
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1143 Ammonium sulfate.

(a) *Product.* Ammonium sulfate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1155 Bentonite.

(a) *Product.* Bentonite.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1165 Butane.

(a) *Product.* Butane.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1191 Calcium carbonate.

(a) *Product.* Calcium carbonate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1193 Calcium chloride.

(a) *Product.* Calcium chloride.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1195 Calcium citrate.

(a) *Product.* Calcium citrate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1199 Calcium gluconate.

(a) *Product.* Calcium gluconate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used

in accordance with good manufacturing or feeding practice.

§ 582.1205 Calcium hydroxide.

(a) *Product.* Calcium hydroxide.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1207 Calcium lactate.

(a) *Product.* Calcium lactate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1210 Calcium oxide.

(a) *Product.* Calcium oxide.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1235 Caramel.

(a) *Product.* Caramel.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1240 Carbon dioxide.

(a) *Product.* Carbon dioxide.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1275 Dextrins.

(a) *Product.* Dextrins of average molecular weight below 100,000.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1320 Glycerin.

(a) *Product.* Glycerin.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1324 Glyceryl monostearate.

(a) *Product.* Glyceryl monostearate.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1355 Helium.

(a) *Product.* Helium.
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1366 Hydrogen peroxide.

(a) *Product.* Hydrogen peroxide.
 (b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a bleaching agent in accordance with good manufacturing or feeding practice.

§ 582.1400 Lecithin.

(a) *Product.* Lecithin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1425 Magnesium carbonate.

(a) *Product.* Magnesium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1428 Magnesium hydroxide.

(a) *Product.* Magnesium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1431 Magnesium oxide.

(a) *Product.* Magnesium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1480 Methylcellulose.

(a) *Product.* U.S.P. methylcellulose, except that the methoxy content shall not be less than 27.5 percent and not more than 31.5 percent on a dry-weight basis.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1500 Monoammonium glutamate.

(a) *Product.* Monoammonium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1516 Monopotassium glutamate.

(a) *Product.* Monopotassium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1540 Nitrogen.

(a) *Product.* Nitrogen.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1585 Papain.

(a) *Product.* Papain.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1613 Potassium bicarbonate.

(a) *Product.* Potassium bicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used

in accordance with good manufacturing or feeding practice.

§ 582.1619 Potassium carbonate.

(a) *Product.* Potassium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1625 Potassium citrate.

(a) *Product.* Potassium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1631 Potassium hydroxide.

(a) *Product.* Potassium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1643 Potassium sulfate.

(a) *Product.* Potassium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1655 Propane.

(a) *Product.* Propane.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1666 Propylene glycol.

(a) *Product.* Propylene glycol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1685 Rennet.

(a) *Product.* Rennet (rennin).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1711 Silica aerogel.

(a) *Product.* Silica aerogel as a finely powdered microcellular silica foam having a minimum silica content of 89.5 percent.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a component of antifoaming agents in accordance with good manufacturing or feeding practice.

§ 582.1721 Sodium acetate.

(a) *Product.* Sodium acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1736 Sodium bicarbonate.

(a) *Product.* Sodium bicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1742 Sodium carbonate.

(a) *Product.* Sodium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1745 Sodium carboxymethylcellulose.

(a) *Product.* Sodium carboxymethylcellulose is the sodium salt of carboxymethylcellulose not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25° C.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1748 Sodium caseinate.

(a) *Product.* Sodium caseinate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1751 Sodium citrate.

(a) *Product.* Sodium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1763 Sodium hydroxide.

(a) *Product.* Sodium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1775 Sodium pectinate.

(a) *Product.* Sodium pectinate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1781 Sodium aluminum phosphate.

(a) *Product.* Sodium aluminum phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1792 Sodium sesquicarbonate.

(a) *Product.* Sodium sesquicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1804 Sodium potassium tartrate.

(a) *Product.* Sodium potassium tartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1901 Triacetin.

(a) *Product.* Triacetin (glyceryl triacetate).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1973 Beeswax.

(a) *Product.* Beeswax (yellow wax).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1975 Bleached beeswax.

(a) *Product.* Bleached beeswax (white wax).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1978 Carnauba wax.

(a) *Product.* Carnauba wax.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Subpart C—Anticaking Agents

§ 582.2122 Aluminum calcium silicate.

(a) *Product.* Aluminum calcium silicate.
(b) *Tolerance.* 2 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing or feeding practice.

§ 582.2227 Calcium silicate.

(a) *Product.* Calcium silicate.
(b) *Tolerance.* 2 percent and 5 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used at levels not exceeding 2 percent in table salt and 5 percent in baking powder in accordance with good manufacturing or feeding practice.

§ 582.2437 Magnesium silicate.

(a) *Product.* Magnesium silicate.
(b) *Tolerance.* 2 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing or feeding practice.

§ 582.2727 Sodium aluminosilicate.

(a) *Product.* Sodium aluminosilicate (sodium silicoaluminate).
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance

with good manufacturing or feeding practice.

§ 582.2729 Hydrated sodium calcium aluminosilicate.

(a) *Product.* Hydrated sodium calcium aluminosilicate (sodium calcium silicoaluminate).
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing or feeding practice.

§ 582.2906 Tricalcium silicate.

(a) *Product.* Tricalcium silicate.
(b) *Tolerance.* 2 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing or feeding practice.

Subpart D—Chemical Preservatives

§ 582.3013 Ascorbic acid.

(a) *Product.* Ascorbic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3021 Benzoic acid.

(a) *Product.* Benzoic acid.
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.1 percent in accordance with good manufacturing or feeding practice.

§ 582.3041 Erythorbic acid.

(a) *Product.* Erythorbic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3081 Propionic acid.

(a) *Product.* Propionic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3089 Sorbic acid.

(a) *Product.* Sorbic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3109 Thiodipropionic acid.

(a) *Product.* Thiodipropionic acid.
(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3149 Ascorbyl palmitate.

(a) *Product.* Ascorbyl palmitate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3169 Butylated hydroxyanisole.

(a) *Product.* Butylated hydroxyanisole.
(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3173 Butylated hydroxytoluene.

(a) *Product.* Butylated hydroxytoluene.
(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3189 Calcium ascorbate.

(a) *Product.* Calcium ascorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3221 Calcium propionate.

(a) *Product.* Calcium propionate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3225 Calcium sorbate.

(a) *Product.* Calcium sorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3280 Dilauryl thiodipropionate.

(a) *Product.* Dilauryl thiodipropionate.
(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3336 Gum guaiac.

(a) *Product.* Gum guaiac.
(b) *Tolerance.* 0.1 percent (equivalent antioxidant activity 0.01 percent).
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in edible fats or oils in accordance with good manufacturing or feeding practice.

§ 582.3490 Methylparaben.

(a) *Product.* Methylparaben (methyl p-hydroxybenzoate).
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.1 percent in accordance with good manufacturing or feeding practice.

§ 582.3616 Potassium bisulfite.

(a) *Product.* Potassium bisulfite.
(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B₁.

§ 582.3637 Potassium metabisulfite.

(a) *Product.* Potassium metabisulfite.
(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B₁.

§ 582.3640 Potassium sorbate.

(a) *Product.* Potassium sorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3660 Propyl gallate.

(a) *Product.* Propyl gallate.
(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3670 Propylparaben.

(a) *Product.* Propylparaben (propyl p-hydroxybenzoate).
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.1 percent in accordance with good manufacturing or feeding practice.

§ 582.3731 Sodium ascorbate.

(a) *Product.* Sodium ascorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3733 Sodium benzoate.

(a) *Product.* Sodium benzoate.
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.1 percent in accordance with good manufacturing or feeding practice.

§ 582.3739 Sodium bisulfite.

(a) *Product.* Sodium bisulfite.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B₁.

§ 582.3766 Sodium metabisulfite.

(a) *Product.* Sodium metabisulfite.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B₁.

practice, except that it is not used in meats or in food recognized as source of vitamin B₁.

§ 582.3784 Sodium propionate.

(a) *Product.* Sodium propionate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3795 Sodium sorbate.

(a) *Product.* Sodium sorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3798 Sodium sulfite.

(a) *Product.* Sodium sulfite.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B₁.

§ 582.3845 Stannous chloride.

(a) *Product.* Stannous chloride.
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.0015 percent calculated as tin in accordance with good manufacturing or feeding practice.

§ 582.3862 Sulfur dioxide.

(a) *Product.* Sulfur dioxide.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B₁.

§ 582.3890 Tocopherols.

(a) *Product.* Tocopherols.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Subpart E—Emulsifying Agents

§ 582.4101 Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(a) *Product.* Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.4505 Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.

(a) *Product.* Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.4521 Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(a) *Product.* Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.4666 Propylene glycol.

(a) *Product.* Propylene glycol.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Subpart F—Nutrients and/or Dietary Supplements¹

§ 582.5013 Ascorbic acid.

(a) *Product.* Ascorbic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5017 Aspartic acid.

(a) *Product.* Aspartic acid (L- and DL-forms).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5049 Aminoacetic acid.

(a) *Product.* Glycine (aminoacetic acid).
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in animal feeds in accordance with good manufacturing or feeding practice.

§ 582.5065 Linoleic acid.

(a) *Product.* Linoleic acid prepared from edible fats and oils and free from chick-edema factor.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5118 Alanine.

(a) *Product.* Alanine (L- and DL-forms).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5145 Arginine.

(a) *Product.* Arginine (L- and DL-forms).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5159 Biotin.

(a) *Product.* Biotin.

¹ Amino acids listed in this subpart may be free hydrochloride salt, hydrated, or anhydrous form, where applicable.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5191 Calcium carbonate.

(a) *Product.* Calcium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5195 Calcium citrate.

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5201 Calcium glycerophosphate.

(a) *Product.* Calcium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5210 Calcium oxide.

(a) *Product.* Calcium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5212 Calcium pantothenate.

(a) *Product.* Calcium pantothenate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5223 Calcium pyrophosphate.

(a) *Product.* Calcium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5230 Calcium sulfate.

(a) *Product.* Calcium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5245 Carotene.

(a) *Product.* Carotene.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5250 Choline bitartrate.

(a) *Product.* Choline bitartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5252 Choline chloride.

(a) *Product.* Choline chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5260 Copper gluconate.

(a) *Product.* Copper gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe for use at a level not exceeding 0.005 percent in accordance with good manufacturing or feeding practice.

§ 582.5271 Cysteine.

(a) *Product.* Cysteine (L-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5273 Cystine.

(a) *Product.* Cystine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5301 Ferric phosphate.

(a) *Product.* Ferric phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5304 Ferric pyrophosphate.

(a) *Product.* Ferric pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5306 Ferric sodium pyrophosphate.

(a) *Product.* Ferric sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5308 Ferrous gluconate.

(a) *Product.* Ferrous gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5311 Ferrous lactate.

(a) *Product.* Ferrous lactate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5315 Ferrous sulfate.

(a) *Product.* Ferrous sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5361 Histidine.

(a) *Product.* Histidine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5370 Inositol.

(a) *Product.* Inositol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5375 Iron reduced.

(a) *Product.* Iron reduced.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5381 Isoleucine.

(a) *Product.* Isoleucine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5406 Leucine.

(a) *Product.* Leucine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5411 Lysine.

(a) *Product.* Lysine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5431 Magnesium oxide.

(a) *Product.* Magnesium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5434 Magnesium phosphate.

(a) *Product.* Magnesium phosphate (di- and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5443 Magnesium sulfate.

(a) *Product.* Magnesium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5446 Manganese chloride.

(a) *Product.* Manganese chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5449 Manganese citrate.

(a) *Product.* Manganese citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5452 Manganese gluconate.

(a) *Product.* Manganese gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used

in accordance with good manufacturing or feeding practice.

§ 582.5455 Manganese glycerophosphate.

(a) *Product.* Manganese glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5458 Manganese hypophosphite.

(a) *Product.* Manganese hypophosphite.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5461 Manganese sulfate.

(a) *Product.* Manganese sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5464 Manganous oxide.

(a) *Product.* Manganous oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5470 Mannitol.

(a) *Product.* Mannitol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5475 Methionine.

(a) *Product.* Methionine.

(b) [Reserved].

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in animal feeds in accordance with good manufacturing or feeding practice.

§ 582.5477 Methionine hydroxy analog and its calcium salts.

(a) *Product.* Methionine hydroxy analog and its calcium salts.

(b) [Reserved].

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in animal feeds in accordance with good manufacturing or feeding practice.

§ 582.5530 Niacin.

(a) *Product.* Niacin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5535 Niacinamide.

(a) *Product.* Niacinamide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5580 D-Pantothenyl alcohol.

(a) *Product.* D-Pantothenyl alcohol.

(b) *Conditions of use.* This substance is generally recognized as safe when used

in accordance with good manufacturing or feeding practice.

§ 582.5590 Phenylalanine.

(a) *Product.* Phenylalanine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5622 Potassium chloride.

(a) *Product.* Potassium chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5628 Potassium glycerophosphate.

(a) *Product.* Potassium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5634 Potassium iodide.

(a) *Product.* Potassium iodide.

(b) *Tolerance.* 0.01 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt as a source of dietary iodine in accordance with good manufacturing or feeding practice.

§ 582.5650 Proline.

(a) *Product.* Proline (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5676 Pyridoxine hydrochloride.

(a) *Product.* Pyridoxine hydrochloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5695 Riboflavin.

(a) *Product.* Riboflavin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5697 Riboflavin-5-phosphate.

(a) *Product.* Riboflavin-5-phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5701 Serine.

(a) *Product.* Serine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5772 Sodium pantothenate.

(a) *Product.* Sodium pantothenate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5835 Sorbitol.

(a) *Product.* Sorbitol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5875 Thiamine hydrochloride.

(a) *Product.* Thiamine hydrochloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5878 Thiamine mononitrate.

(a) *Product.* Thiamine mononitrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5881 Threonine.

(a) *Product.* Threonine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5892 α -Tocopherol acetate.

(a) *Product.* α -Tocopherol acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5915 Tryptophane.

(a) *Product.* Tryptophane (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5920 Tyrosine.

(a) *Product.* Tyrosine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5925 Valine.

(a) *Product.* Valine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5930 Vitamin A.

(a) *Product.* Vitamin A.

(b) *Conditions of use.* This substance is generally recognized as safe when used

in accordance with good manufacturing or feeding practice.

§ 582.5933 Vitamin A acetate.

(a) *Product.* Vitamin A acetate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5936 Vitamin A palmitate.

(a) *Product.* Vitamin A palmitate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5945 Vitamin B₁₂.

(a) *Product.* Vitamin B₁₂.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5950 Vitamin D₂.

(a) *Product.* Vitamin D₂.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5953 Vitamin D₃.

(a) *Product.* Vitamin D₃.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5985 Zinc chloride.

(a) *Product.* Zinc chloride.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5988 Zinc gluconate.

(a) *Product.* Zinc gluconate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5991 Zinc oxide.

(a) *Product.* Zinc oxide.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5994 Zinc stearate.

(a) *Product.* Zinc stearate prepared from stearic acid free from chick-edema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5997 Zinc sulfate.

(a) *Product.* Zinc sulfate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Subpart G—Sequestrants*

*For the purpose of this subpart, no attempt has been made to designate those sequestrants that may also function as chemical preservatives.

§ 582.6033 Citric acid.

(a) *Product.* Citric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6085 Sodium acid phosphate.

(a) *Product.* Sodium acid phosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6099 Tartaric acid.

(a) *Product.* Tartaric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6185 Calcium acetate.

(a) *Product.* Calcium acetate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6193 Calcium chloride.

(a) *Product.* Calcium chloride.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6195 Calcium citrate.

(a) *Product.* Calcium citrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6197 Calcium diacetate.

(a) *Product.* Calcium diacetate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6199 Calcium gluconate.

(a) *Product.* Calcium gluconate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6203 Calcium hexametaphosphate.

(a) *Product.* Calcium hexametaphosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6215 Monobasic calcium phosphate.

(a) *Product.* Monobasic calcium phosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6219 Calcium phytate.

(a) *Product.* Calcium phytate.
(b) *Conditions of use.* This substance is generally recognized as safe when used

in accordance with good manufacturing or feeding practice.

§ 582.6285 Dipotassium phosphate.

(a) *Product.* Dipotassium phosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6290 Disodium phosphate.

(a) *Product.* Disodium phosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6386 Isopropyl citrate.

(a) *Product.* Isopropyl citrate.
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.02 percent in accordance with good manufacturing or feeding practice.

§ 582.6511 Monoisopropyl citrate.

(a) *Product.* Monoisopropyl citrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6540 Potassium citrate.

(a) *Product.* Potassium citrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6651 Sodium citrate.

(a) *Product.* Sodium citrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6754 Sodium diacetate.

(a) *Product.* Sodium diacetate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6757 Sodium gluconate.

(a) *Product.* Sodium gluconate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6760 Sodium hexametaphosphate.

(a) *Product.* Sodium hexametaphosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6769 Sodium metaphosphate.

(a) *Product.* Sodium metaphosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).
(b) *Conditions of use.* This substance is generally recognized as safe when used

in accordance with good manufacturing or feeding practice.

§ 582.6787 Sodium pyrophosphate.

(a) *Product.* Sodium pyrophosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6789 Tetra sodium pyrophosphate.

(a) *Product.* Tetra sodium pyrophosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6801 Sodium tartrate.

(a) *Product.* Sodium tartrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6804 Sodium potassium tartrate.

(a) *Product.* Sodium potassium tartrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6807 Sodium thiosulfate.

(a) *Product.* Sodium thiosulfate.
(b) *Tolerance.* 0.1 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in salt in accordance with good manufacturing or feeding practice.

§ 582.6810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6851 Stearyl citrate.

(a) *Product.* Stearyl citrate.
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.15 percent in accordance with good manufacturing or feeding practice.

Subpart H—Stabilizers

§ 582.7115 Agar-agar.

(a) *Product.* Agar-agar.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7133 Ammonium alginate.

(a) *Product.* Ammonium alginate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7187 Calcium alginate.

(a) *Product.* Calcium alginate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7255 Chondrus extract.

(a) *Product.* Chondrus extract (carrageenin).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7330 Gum arabic.

(a) *Product.* Acacia (gum arabic).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7333 Gum ghatti.

(a) *Product.* Gum ghatti.
(b) *Conditions of use.* This substance is generally recognized as safe when used

in accordance with good manufacturing or feeding practice.

§ 582.7339 Guar gum.

(a) *Product.* Guar gum.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7343 Locust bean gum.

(a) *Product.* Locust (carob) bean gum.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7349 Sterculia gum.

(a) *Product.* Sterculia gum (karaya gum).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7351 Gum tragacanth.

(a) *Product.* Tragacanth (gum tragacanth).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7610 Potassium alginate.

(a) *Product.* Potassium alginate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7724 Sodium alginate.

(a) *Product.* Sodium alginate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

[FR Doc.76-26299 Filed 9-9-76; 8:45 am]

FRIDAY, SEPTEMBER 10, 1976



PART IV:

ENVIRONMENTAL PROTECTION AGENCY

■

FUEL ECONOMY TESTING, CALCULATION AND EXHAUST EMISSIONS TEST PROCEDURES FOR 1977-1979 MODEL YEAR AUTOMOBILES

**Interim Final Rule Making
and Proposed Rule Making**

Title 40—Protection of Environment
CHAPTER I—ENVIRONMENTAL
PROTECTION AGENCY
 [FRL 603-5]

PART 86—CONTROL OF AIR POLLUTION
FROM NEW MOTOR VEHICLE ENGINES:
CERTIFICATION AND TEST PROCE-
DURES

PART 600—FUEL ECONOMY OF MOTOR
VEHICLES

Fuel Economy Testing for 1978 Model Year
Automobiles and Calculation Procedures
for 1977 and Subsequent Model Year
Automobiles; Exhaust Emissions Test
Procedures for 1978 Model Year Auto-
mobiles and Light Duty Trucks

I. SYNOPSIS OF ACTION

On December 22, 1975, the President signed the Energy Policy and Conservation Act, Pub. L. 94-163, 89 Stat. 871. Title III of this Act amends the Motor Vehicle Information and Cost Savings Act, 15 U.S.C. 1901 et seq. (hereinafter referred to as "the Act") for the purpose of regulating the fuel economy of automobiles. This notice relates primarily to Section 501 of the Act relating to definitions and Section 503 which requires the Administrator of EPA to promulgate rules prescribing testing and calculation procedures which will be used for computation of automobile manufacturers' fuel economy averages for 1978 and subsequent model years. These manufacturer's average fuel economy values will be used by the Secretary of Transportation (hereinafter referred to as "the Secretary") to determine compliance with the minimum fuel economy standards prescribed in Section 502 of the Act.

Due to the time constraints and statutory requirements more fully explained below, this notice contains both interim final fuel economy testing and calculation procedures for the 1978 model year and proposed procedures for 1979 and subsequent model years.

In addition to the interim final promulgation of the regulations applicable to the 1978 model year, several provisions which were previously proposed for the 1977 model year (41 FR 21002, May 21, 1976) are being published as final for 1977 in this rulemaking, rather than with the regulations requiring the labeling of 1977 and subsequent model year automobiles, as they are essential to the understanding and implementation of this action.

These procedures provide means by which EPA will test automobiles, or cause them to be tested, and calculate an average fuel economy for each manufacturer's product line. EPA will select test vehicles from among all of the various combinations of models, engines, transmissions and drive trains offered for sale by the manufacturers. Since there are many thousands of such combinations, EPA will not be collecting data from every such combination. However, a high percentage of the vehicles in each manufacturer's product

line will be represented by EPA test vehicle selections. In general, the increase in the number of test vehicles over the number now being tested for emissions certification and fuel economy labeling purposes will be quite modest.

In addition to fuel economy testing and calculation procedures, EPA is hereby promulgating and proposing changes to the test procedures used for measuring both exhaust emissions and city fuel economy for 1978 model year automobiles and light duty trucks. These changes are intended to improve the accuracy or representativeness of the tests, but not to affect their stringency.

A detailed explanation of the actions taken herein and the reasons for EPA's promulgation of final regulations for the 1978 model year without the prior issuance of a formal Notice of Proposed Rule Making (NPRM) are set forth below.

II. 1978 FINAL RULE MAKING

Section 503 of the Act provides that "Testing and calculation procedures applicable to a model year * * * shall be promulgated not less than 12 months prior to the model year to which such procedures apply." Section 502 of the Act provides that fuel economy standards will first go into effect for the 1978 model year. Thus, final regulations are required by the Act to be promulgated no later than twelve months prior to the beginning of the 1978 model year.

The Act provides a definition of model year for individual manufacturers, but not for the industry as a whole. EPA, in consultation and coordination with the Department of Transportation (DOT), has determined that no specific date can be deemed the beginning of a model year for the entire industry. However, for the domestic manufacturers (whose model years traditionally begin earlier than importers') model year production has in the past generally begun in August. Consequently, for the purposes of the statutory deadline in Section 503 of the Act, EPA finds that the 1978 model year will begin no earlier than August, 1977, and that these regulations are required to be promulgated during August, 1976, to the extent that they are applicable to the 1978 model year.

The Energy Policy and Conservation Act was enacted on December 22, 1975, as noted previously. Since then considerable time and intensive interagency effort have been devoted to developing, drafting and reviewing these regulations. During this same period, regulations have been prepared pursuant to Section 506 of the Act for the mandatory fuel economy labeling program. An NPRM was issued for labeling on May 21, 1976, 41 FR 21002. EPA has consulted and coordinated with DOT and has consulted with the Federal Energy Administration and the Federal Trade Commission as required by the Act. The complexity of the issues that had to be resolved and the efforts required to prepare this action and coordinate it with the other interested agencies, together with the deadline in the

Act, have made it impossible to issue rules for 1978 with prior issuance of an NPRM.

Section 553 of Title 5 of the United States Code (pertaining to administrative procedure) provides for the promulgation of regulations without prior issuance of an NPRM, "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." For the reasons cited above, EPA finds that issuance of an NPRM and provision of a public comment period for the 1978 model year are impracticable. EPA further finds that failure to promulgate regulations prior to the end of August, 1976 would risk rendering the 1978 fuel economy standards substantially unenforceable (at least for those manufacturers beginning production in August) and that this result would be contrary to the public interest as articulated by the Congress in the Act.

Nevertheless, EPA has made every effort to inform interested parties of its plans and has attempted to receive comments from these parties prior to taking this action. Various drafts have been offered directly to industry members, trade associations, consumer groups and environmental groups and were placed on the public record at EPA. The availability of the drafts was announced at an open meeting held on March 17, 1976 by EPA (pursuant to notice published in the FEDERAL REGISTER, 41 FR 6121, February 11, 1976) and the contents of early drafts were explained by EPA at the meeting. Comments were solicited and received, and numerous consultations have taken place between EPA staff, Department of Transportation staff and various interested parties.

In a series of consultations with interested parties who had reviewed drafts of this action, including manufacturers and the other interested agencies, several significant deficiencies were brought to EPA's attention regarding the form and content of the drafts. The direction ultimately taken by EPA in formulating this action, the criteria used for evaluating alternative courses of action available to EPA, and the drafting of the regulatory provisions now contained in this action were all significantly affected by these consultations.

Thus, the procedures set forth for the 1978 model year in Part 86, Subparts A and B are final and the procedures set forth for the 1977 and 1978 model years in Part 600 are final. All of the regulatory provisions contained in this notice which are applicable beginning in 1979 are proposed and will be amended in accordance with the record of this proceeding or as otherwise appropriate. Based on comments received, EPA will endeavor to issue any necessary and appropriate amendments for 1978 which are technical or clerical in nature or which will otherwise not prejudice the interests of affected parties.

III. EFFECTIVE DATES

The regulatory provisions contained in this action become effective as follows:

(1) The provisions applicable to the 1978 model year in Parts 86 and 600: §§ 86.078-37, 86.113-78, 86.114-78, 86.121-78, 86.123-78, 86.135-78, 86.136-78, 86.137-78, 86.142-78, 86.144-78, 600.101-78 through 600.113-78 and 600.501-78 through 600.512-78 are hereby promulgated on an interim final basis for the 1978 model year;

(2) The provisions listed above in Parts 86 and 600 are hereby proposed for 1979 and subsequent model years.

(3) The provisions in §§ 86.079-2, 86.079-24, 86.113-79, 86.129-79 pertaining to test procedures changes are not effective for the 1978 model years, but are proposed for 1979 and subsequent model years.

(4) Section 600.511-80 is hereby proposed for the 1980 model year.

In addition to the sections enumerated above, some provisions included in this notice for 1977 implementation were originally proposed by EPA in connection with another action required by the Act. On May 21, 1976, EPA issued an NPRM relating to the fuel economy labeling program required by Section 506 of the Act. See, *Fuel Economy Regulations and Test Procedures for 1977 and Later Model Automobiles*, 41 FR 21002 (hereafter referred to as the "labeling regulations"). These labeling regulations contain certain definitions and procedures essential to the calculation of manufacturer's fuel economy averages.

It was originally intended that the labeling regulations would be promulgated before the regulations contained in this notice, but this has become impossible. Therefore, certain provisions contained in the labeling regulations have been included in this notice for 1977 implementation. These include the provisions in Part 600, Subparts A and C [except §§ 600.005, 600.007(e), 600.206 (b) and (c) and 600.207 (c) and (d)]. Comments were solicited and received from manufacturers on certain of these provisions. One comment expressed the concern that the use of EPA approved data might constitute acceptance of the data's validity by the manufacturer and would, as a consequence, jeopardize the right to appeal under § 600.009-77. It is the Agency's opinion that the only position consistent with the preservation of a manufacturer's right to appeal is that manufacturers who contest the fuel economy data to be used on the fuel economy label must label their vehicles with the fuel economy data determined and/or approved by the Administrator and may sell vehicles with this label, but that the use of this fuel economy data does not constitute acceptance of the data's validity or in any way prejudice the manufacturer's right to appeal pursuant to § 600.009-77.

Other comments were received questioning the requirement of section 600.207 that manufacturers must supply test results from vehicles representing the highest production volume configuration

in each base level not otherwise represented by a test vehicle. It was pointed out that the highest selling configuration might not be readily derived from already existing test vehicles through the changing of components or through testing at alternative weights, both options available under the regulations. Consequently, it was suggested that EPA accept data from such a derivative, even though a car so derived from an existing test vehicle might not represent the highest selling configuration in an otherwise unrepresented base level. EPA does not anticipate this to occur except in relatively rare cases. In most instances, untested base levels will be subject to representation by test results from an already tested vehicle which has been simply altered as to some components or which will be tested at multiple inertia weights. Thus the burden imposed on the industry by this section of the regulations is quite small. On the other hand, it is important that base levels be represented by those vehicles which most closely approximate the fuel economy of the base level as a whole, i.e., the highest selling configuration. EPA is compromising by accepting data from certification vehicles to represent base levels even though the certification vehicles may not represent highest sellers. This is being done so that multiple testing within a base level is not required for labeling. However, in cases in which there is no data for a base level, it is only reasonable that EPA require the most representative configuration to be tested, particularly in light of the modest burden this entails.

Comments were also received concerning the degree of decimal precision to be employed in calculating fuel economy values. Some commenters made the erroneous argument that all test results and calculations should be expressed to the highest degree of precision possible since, in a unique situation, two different final fuel economy results could be calculated. What they did not point out, however, is that increasing precision, i.e., the number of decimal places reported, does not necessarily improve accuracy. EPA has determined that a single test on a vehicle provides fuel economy information accurate to the nearest whole MPG.

Since the individual test results are accurate to the nearest whole MPG, accepted data reduction methodology indicates that for the purpose of subsequent calculations, fuel economy test values may be expressed to one more decimal place, i.e., the nearest tenth of a mile per gallon. This rationale and methodology were employed consistently in the proposed regulations which, therefore, do not require revision for the reporting provisions of fuel economy test values.

However, the Agency recognizes that in certain unique circumstances, the practice of rounding off each intermediate calculation to the nearest 0.1 MPG could result in a different and perhaps less accurate final general label value.

Therefore, in order to minimize even the slight possibility of introducing error due to successive round-off, all intermediate calculated values will be rounded to a four decimal place precision (i.e., 0.0001 MPG). The final report values (e.g., general and specific label values) will continue to be rounded off to the nearest whole MPG.

The high level of coordination and cooperation between EPA and interested parties concerning the received comments and all aspects of this action has enabled the promulgation of these provisions for 1977 and subsequent model years along with the sections enumerated earlier.

IV. OTHER STATUTORY REQUIREMENTS

These regulations fulfill the requirements of the Energy Policy and Conservation Act imposed upon EPA regarding testing and calculation procedures for determining a manufacturer's average fuel economy. Regulations for fuel economy labeling as required by the Act for 1977 and later model years have previously been proposed by EPA, as noted above. Final labeling regulations for the 1976 model year are promulgated on March 19, 1976 (41 FR 11506). Procedures for testing and evaluation of retrofit fuel economy devices under Section 511 of the Act will be issued by EPA by separate notice to follow.

As required by the Act, consultation and coordination between EPA and the Department of Transportation (DOT) have been carried out. In addition, EPA has consulted with the Federal Energy Administration (FEA) and various other interested parties as noted above.

Comments are hereby requested from interested parties on the provisions set forth below. Comments on either the proposed actions for 1979 and subsequent model years or the interim final action for 1978 will be considered. However, amendments to the 1978 interim final regulations will only be made to the following limited extent:

- (1) That any such changes are necessary and appropriate, and
- (2) That any such changes will prejudice the interests of parties affected thereby, or
- (3) That such changes are merely technical or clerical in nature.

V. TESTING, SAMPLING AND CALCULATION PROCEDURES

The following is a more detailed explanation of the regulatory provisions contained in this action which set forth the means by which EPA will select cars for testing, test the cars or cause them to be tested, and calculate fuel economy averages for each manufacturer of passenger automobiles.

A. *Basic Definitions.* Several basic definitions are employed throughout this preamble and the regulations themselves. EPA believes that an introductory discussion of these terms is therefore in order so that the reader might better understand this action. (Each of these terms is defined formally in the regulations which follow this preamble.)

The Act specifies fuel economy standards for passenger automobiles. A *passenger automobile* is any automobile which is rated at 6000 pounds gross vehicle weight or less and which the Secretary of DOT determines is manufactured primarily for use in the transportation of not more than 10 individuals. (Under the provisions of Section 501 of the Act, the Secretary of Transportation can expand the definition to include heavier vehicles.) All passenger automobiles so designated by the Secretary will be included in the calculation of each manufacturer's fuel economy average.

For fuel economy purposes, the first major subdivision of a manufacturer's product line is *car line*. A *car line* denotes a group of vehicles within a make or car division which has a degree of commonality in construction. Car line does not consider any level of decor or opulence and is generally not distinguished by characteristics such as roof line, number of doors, seats or windows, although station wagons are considered distinct car lines from sedans. For example, in the 1976 EPA/FEA Gas Mileage Guide for New Car Buyers, Buick, a division of General Motors, had listed nine car lines: Electra, Skylark, Opel, Century/Regal, Century Wagon, LeSabre, Estate Wagon, Skyhawk and Riviera.

Within any car line, a number of model types may exist. *Model type* means a unique combination of car line, basic engine, and transmission class. This definition of model type incorporates two key parameters which most affect fuel economy and which are capable of being understood and used by the average consumer. Thus, a major function of model type is to provide a meaningful concept for publishing fuel economy information (since model type corresponds to nameplates known to the general public) as well as being used to calculate manufacturers' average fuel economy.

An additional system of classification is used for subdividing a manufacturer's product line into smaller groups for determining test requirements, both for the purpose of calculating manufacturers' averages and for calculating fuel economy label values. This alternative system classifies each manufacturer's product line into base levels. A *base level* is a unique combination of inertia weight class, basic engine and transmission class. (Note that base level is nearly the same as model type except that weight is substituted for car line.) The fuel economy for each model type is simply the sales-weighted, harmonic average¹ of the fuel economy of each base level comprising the model type. The significance of the concept of base level is that the vehicle characteristics which define a base level are those that most profoundly affect fuel economy. At least one vehicle from each base level produced by the manufacturer must be tested in

order to calculate the fuel economy results for a manufacturer. Again using the Buick example, a typical base level would be a 3500 pound vehicle, 231 cubic inch, 6 cylinder engine with 2 barrel carburetor, catalyst, and manual transmission. *Basic engine* distinguishes engines of a particular displacement, number of cylinders, fuel system, and catalyst usage. *Transmission class* is the basic type of transmission, i.e., manual, automatic, or semiautomatic.

An additional level of delineation is necessary to identify individual test vehicles. Base levels are subdivided into vehicle configurations. A *vehicle configuration* is defined as a unique combination of inertia weight class, basic engine, and transmission class (all of which determine a base level) plus engine code, transmission configuration, and axle ratio. *Engine code* goes beyond the definition of basic engine by isolating different variations of carburetor, distributor, and other key engine and emission control system components. *Transmission configuration* considers more than just manual or automatic and distinguishes transmissions by their number of forward gears, e.g., three-speed manual and four-speed manual. An example of a vehicle configuration is 3500 pound, 231 cubic inch, 6 cylinder, 2 barrel carburetor engine of engine code 4, with catalyst, 4-speed manual transmission and 2.56 axle ratio.

As more fully explained below, the individual vehicles which will be tested pursuant to these rules will be specified as *vehicle configurations*. Data from the vehicle configurations tested within a base level will be combined (weighted as to production projections or actual production figures) to arrive at a fuel economy value for each base level. These base level values will in turn be combined to yield fuel economy values for each model type. Pursuant to the Act, each manufacturer's fuel economy average will be the harmonic, production-weighted average fuel economy of that manufacturer's model types.

B. Calculation of Average Fuel Economy. Beginning with the 1978 model year, the average fuel economy of passenger automobiles produced by each manufacturer is required to be no less than 18.0 miles per gallon (MPG), with the standard gradually increasing to 27.5 MPG in 1985. (The Secretary has authority to adjust these standards somewhat under circumstances specified in the Act.) Failure to meet the standard applicable in any given year subjects a manufacturer to a civil penalty. However, this penalty can be offset by a credit if the manufacturer exceeded the applicable standard in the year previous to the violation or if he exceeds the standard in the year following the violation.

The penalties provided for in the Act are quite substantial—five dollars for each passenger automobile produced for each 0.1 MPG that the applicable standard exceeds the manufacturer's average fuel economy for that year. Credits are assessed by a similar formula at the same rates. For a manufacturer who failed to

meet the standard by a mere one tenth of a mile per gallon in a year in which he produced five million passenger automobiles, the penalty specified by the Act would be 25 million dollars. (However, the penalties accruing to the nation as a result of this failure would amount to 23.2 million fewer gallons of fuel available for consumption each year and an additional annual cost to the American public of \$15,000,000².)

Due to the potential for such large penalties and credits based on shifts of tenths of an MPG, and due to the potentially large differences in aggregate fuel consumption that small changes in average fuel economies may represent, it is in the interest of both the government and the industry that manufacturers' calculated fuel economy averages be as truly representative of manufacturers' product line fuel economies as practicable. An inadequate testing and calculation plan could result in the imposition of an undue financial burden on a manufacturer in the form of large, unwarranted penalties, or costly and unwarranted vehicle modifications, or production shifts if the calculated value were too low. Alternatively an incorrectly high calculated average could deprive the nation of the total fuel savings envisioned by the Act and could inappropriately give the manufacturer a credit.

EPA's role in this program is to measure the fuel economy of manufacturers' passenger automobiles, to calculate manufacturer's fuel economy averages and to transmit these data and calculations to DOT so that the Secretary can make determinations of compliance and assess penalties as required.

The calculated manufacturers' average fuel economies are a function of three factors—production figures, the mathematical methodology used and the vehicle test data included in the calculation. Production data are discussed at more length below. The mathematical methodology is not an issue since the Act specifies that the average will be the harmonic, production-weighted average of the model type fuel economies determined for each manufacturer. The last of these factors, the vehicle test data to be included, is not so precisely specified in the Act.

Although the Act does not specify which cars EPA must test for the purposes of calculating manufacturers' averages under Section 503, it does provide some guidance. EPA is directed to conduct fuel economy tests for the purposes of this section in conjunction with emissions tests carried out under Section 206 of the Clean Air Act, 42 U.S.C. 1857 f-5, to the extent practicable. Since it is essential to know that fuel economy data is being derived from a vehicle that also meets the emission standards as required by the Clean Air Act, and since the emissions test is identical to the urban fuel economy test, and since urban fuel

² This assumes five million cars produced, a standard of 18.0 MPG, average annual mileage accumulation of 15,000 miles and an average fuel cost of \$0.65 per gallon.

¹ The harmonic average fuel economy is computed by taking the inverse of average fuel consumption where consumption is expressed as gallons per mile.

economy and emissions measurements are made simultaneously, Congress' instructions in this regard are well taken. However, Congress also provided the Administrator of EPA with general authority to issue regulations prescribing the means by which fuel economy values will be measured and averages calculated. EPA has found it necessary to use this general authority to augment the fleet of cars tested for emissions purposes in order to have tested a fleet which will be representative of manufacturers' product lines for fuel economy purposes as well as emissions.

For emissions purposes, EPA groups manufacturers' various designs by those characteristics most significant to emissions performance, rather than fuel economy. EPA then selects individual designs for testing according to the requirements of the Clean Air Act. Since the emissions standards only require EPA to make a pass/fail determination, rather than to quantify the degree of passage or failure, and since every design tested must meet the emissions standards in order to be sold, EPA selects many designs for testing which are judged to be the least likely within an emissions category or grouping of designs (known as "engine families") to pass the emissions test.

For the purpose of calculating manufacturer's fuel economy averages, EPA's testing needs are quite different from those under the Clean Air Act. In the first instance, EPA must group manufacturers' designs by those characteristics which most affect fuel economy. Since some vehicle characteristics affect fuel economy more than emissions, and vice versa, these groupings are not always consistent with engine families. Moreover, under Section 503 of the Act, EPA must quantify the degree of passage or failure for a manufacturer's entire line; how an individual car performs is not at issue. Thus, an emissions test fleet containing a disproportionate number of cars judged to be the least likely to meet emissions standards (which coincidentally are likely to have somewhat low fuel economies relative to many cars with higher sales volumes) is not representative of a manufacturer's overall production for fuel economy purposes. For these reasons, EPA has found it necessary to augment the fleet of cars tested for emissions in order to provide a data base from which fuel economy averages can be calculated with enough accuracy to enable the Administrator to have a reasonable basis for the values calculated and to enable the Secretary to bring successful enforcement of actions.

The emissions test fleet is already augmented by the addition of cars used for fuel economy labeling purposes. This practice has been proposed to continue under Section 506 of the Act in the labeling program for 1977 and later years. (See, 41 FR 21002, May 21, 1976.) However, the addition of these cars alone is not adequate for the purposes of Section 503 of the Act since some configurations with high production volumes would still not be tested. Under the labeling pro-

gram, fuel economy estimates are rounded to the nearest whole MPG. This provides a means by which consumers can compare the relative fuel economy of new cars, a purpose for which greater precision is not required. However, the data used to generate these whole MPG values cannot provide the precision needed to make Section 503 determinations (with their potentially enormous consequences) and consequently would not provide a reasonable basis for assessing penalties.

VI. ALTERNATIVE APPROACHES TO THE SELECTION OF FUEL ECONOMY TEST VEHICLES

Several alternative approaches to the selection of fuel economy test vehicles (hereinafter referred to as "fuel economy data vehicles") were examined by EPA in close coordination and consultation with DOT. EPA employed the following criteria in selecting among the various alternative approaches to picking fuel economy data vehicles:

- (1) The degree to which the resulting fleet of test vehicles would yield a calculated average representative of the manufacturer's actual fleet average;^a
- (2) The enforceability of a penalty assessed on the basis of a manufacturer's calculated value being below the standard;
- (3) The degree to which the vehicle selection scheme would permit a manufacturer to respond with mid-year product design or production mix changes to remedy a potential non-compliance situation; and
- (4) The resources required by both industry and EPA to conduct the necessary testing (for which the public ultimately pays).

All of the alternatives considered for augmenting the emissions and labeling test fleets fall into one of two categories. Either they amount to the accumulation of data intended to provide a statistically valid sampling of the manufacturer's vehicles, or they provide a representative, rather than statistical, sample of each manufacturer's line. However, just as an approach only employing emissions program data could not seriously be considered for calculating manufacturer's averages, a pure statistical sampling approach was quickly dismissed as a possibility. EPA and DOT did, however, consider in detail several alternative means of sampling which were variations on either the representative sampling scheme (herein adopted) or which were hybrids combining aspects of both representative and statistical sampling. These two basic alternatives, the adopted approach and the hybrid, are discussed below. Alternative 1, the hybrid "Statistical Sampling Approach," specifies the minimum number of vehicles which would have to be tested to determine an average fuel economy for each manufacturer

^a A manufacturer's actual fleet average is the average fuel economy that would be measured using the prescribed test procedures if every car produced were actually tested.

at a predetermined level of accuracy and statistical confidence. Alternative 2, the "Representative Approach" specifies a relatively low level of additional testing, over and above emissions and fuel economy labeling testing, and provides manufacturers with secure base fuel economy values, i.e., the measured fuel economy of each base level does not change unless the production mix changes or the manufacturer elects to make mid-year design changes.

STATISTICAL SAMPLING APPROACH

In this approach manufacturers must test the minimum number of vehicles required to calculate average fuel economy values to a predetermined level of confidence. This minimum number is a function of:

- (1) Base level variability,
- (2) Minimum incremental accuracy required,
- (3) Manufacturer's calculated average fuel economy,
- (4) Desired confidence level about the average,
- (5) The level of the standard.

EPA and DOT examined several types of statistical sampling approaches against the criteria enumerated above. All of these sampling plans suffered from the same problems, i.e., if enough cars were to be tested to ensure the enforceability of the standard, each manufacturer would have to test a great many cars and the manufacturer would not know his precise fuel economy until it was too late to make mid-year changes which would either bring him into compliance or at least reduce the degree by which he failed to meet the standard. Under the best of these variants of statistical sampling, by 1985, most manufacturers would have to test thousands of cars annually and for the industry as a whole, the test burden would be tens, if not hundreds, of thousands of cars (even though only manufacturers whose average was close to, or below, the standard would have to conduct a full test program). The cost of such an extensive program of testing, exclusive of the costs of new test facilities which would have to be built, would be in the hundreds of millions of dollars.

(A more detailed discussion of the statistical sampling schemes analyzed by EPA and DOT is available on the public record of this rule making proceeding.)

EPA has rejected the use of a statistical sampling plan for the following reasons:

- (1) The number of tests required to be conducted would be much more costly than is justified, if not altogether prohibitive.
- (2) The value of a statistical sampling plan is primarily that it is possible to preselect a test fleet which characterizes the fleet produced by a manufacturer and measure the fuel economy of that fleet within specified confidence intervals. However, in order to keep the level of testing down to even the infeasible numbers referred to above, it is necessary to assume a degree of variability within base levels which cannot be verified. (It

would take more testing to prove this variability for each base level than to calculate the average itself.) Thus a manufacturer could challenge a calculated average on the grounds that EPA's assumed variability was lower than the manufacturer's actual variability and that EPA consequently had not caused enough cars to be tested.

(3) Due to the large number of cars that would have to be tested, manufacturers could not conduct all of the requisite tests prior to, or early in, the model year. Testing would have to be distributed throughout the model year and might have to extend beyond the end of production for the model year. Consequently, manufacturers would not know if they had met the standard applicable to a given year until it was too late to change the mix of designs in their product lines (to increase the number of cars of configurations with good fuel economy they were producing) or to effect design changes to improve fuel economy. Since the purpose of the Act is to reduce fuel consumption and not to collect penalties, it is essential that manufacturers' opportunities to comply not be curtailed in this way.

Unlike statistical approaches to sampling, representative sampling plans rely on the testing of enough cars within each base level so that the fuel economy of production vehicles within each base level is adequately represented by the vehicles tested. An additional feature of the particular representative sampling plan agreed to in the course of consultation and coordination between EPA and DOT is that fuel economy values for base levels would not change during a model year unless the proportions of the different designs in the product line changed or the manufacturer elected to make changes in the designs themselves (the latter known as "running changes").

Under the adopted representative sampling plan, EPA would make a preliminary calculation of each manufacturer's average fuel economy soon after the beginning of the model year. This calculation would employ five sources of data (weighted according to their contribution to total projected production) as follows:

- (1) Original emission certification test vehicles ("emission data vehicles");
- (2) Vehicles required to be tested for fuel economy labeling;
- (3) Vehicles representing running changes made early in the year which are required to be tested for emissions purposes;
- (4) Vehicles representing high production volume configurations in significant base levels;
- (5) Vehicles submitted voluntarily by the manufacturer.

After this preliminary calculation is made, manufacturers will have the option of petitioning the Administrator to be exempted from providing additional test data representing running changes implemented after the preliminary calculation is made. The exemption would be granted if EPA determined that the pre-

liminary average was sufficiently above the standard so that, in spite of any reasonably foreseeable changes in the production mix and the potential change in the average due to running changes, there would be little likelihood that the manufacturer would be below the applicable standard in the year for which the calculation was being made and so that there would be little likelihood that the manufacturer would need a credit in the following year. (As noted earlier, the Act contains a provision offsetting penalties for failure to meet applicable standards if the standards for the prior year of failure or following the year of failure were exceeded.)

EPA will establish criteria for the granting of such exemptions based on the number of cars tested prior to the calculation of the preliminary average, the applicable standard, the potential for change in the average due to running changes, and other factors as appropriate. Comments are requested on the criteria that should be used for making these determinations and the manner of their application.

EPA at one time considered granting such petitions for exemption only if, based on the preliminary calculation of a manufacturer's average, the manufacturer was not only in no danger of failing to meet the standard in a given year (so that no penalty would be assessed), but if the manufacturer was also already clearly meeting the standard for the following year (so that no credit would be necessary).

Thus, it is not EPA's intention to require unnecessary testing in situations in which the preliminary data is adequate. If a manufacturer is in no danger of failing to meet a standard or of needing a credit to offset a penalty which might be assessed in the future, irrespective of production mix or running changes, no useful purpose is served by requiring the manufacturer to incur the costs of a full test program. However, if there may either be a penalty or credit based on a test program, the preliminary calculation would be inadequate as a manufacturer could artificially inflate a credit or reduce the size of a penalty by manipulating his production projections or his running changes.

EPA now believes, and DOT concurs, that these interests are adequately addressed if exemptions from full testing are granted under either of the following conditions:

(1) Based on the preliminary calculation of a manufacturer's average (with the application of the types of criteria noted above), there is a high degree of assurance that the manufacturer is meeting, and will continue to meet, the standards both for a given year and the following year; or

(2) Based on the preliminary calculation as above, there is a high degree of assurance that the manufacturer is meeting and will continue to meet the standard only for a given year (but may need a credit in the following year), if the manufacturer waives any credit that might be based on the preliminary calculation.

If a manufacturer fails to obtain an exemption, the agency would require that each running change implemented during the model year be evaluated for possible effects on the fuel economy of "significant" base levels.* EPA is requiring that data for the configuration representing the most production units that are affected by the running change and that are also within the top 90 percent (based on proportion of production) of a significant base level be submitted. These data could be the results of testing or derived by an analytical technique such as an approved regression analysis.

Based upon data available from the 1976 model year certification and labeling programs, an average of less than 5 additional vehicles per manufacturer would be required to represent 90 percent of the projected production of the significant base levels for the four large domestic manufacturers. However, insufficient data exist to accurately assess the additional test burden resulting from evaluating mid-year design changes, although it is possible to predict that this testing will be well within the limits of feasibility. Furthermore, the number of running change tests required will be ultimately within the control of the manufacturers since running changes themselves are not required by any regulations.

The required resource levels for this approach are reasonable and consistent with apparent Congressional intent. This approach should be at least as enforceable as any feasible statistical approach since any manufacturer who does not believe that the testing required by EPA provides a reasonable basis for making compliance determinations may submit additional data as provided in the Act.

Not only is the direct economic cost of this approach less than that of the statistical approach as a result of a lower test volume, but the lower number of required tests will provide the manufacturers with the opportunity to make mid-year adjustments that might be necessary to meet the fuel economy standard. A requirement for as large a number of tests as required under the statistical approach would dictate the distribution of mandated testing over the entire model year due to limited test facilities. Under the statistical approach the manufacturer would be placed in the untenable position of not knowing the fuel economy values used in calculating his average until half-way or even later into the model year. If then he found out that he was in jeopardy of failing the standard, little time would be left to correct the situation except through drastic production mix shifts. By providing this fuel economy data information early in the model year, the representative approach minimizes these problems and gives manufacturers more flexibility and opportunity to meet standards by either shifting model mix or by making mid-year design modifications.

* A significant base level is any that represents 1 percent or more of a manufacturer's production.

The selected approach has an additional advantage over the statistical approach in that it makes optimum use of certification and labeling test volume. All certification and fuel economy labeling data are used to meet test data requirements which might have to be satisfied by different vehicles under other sampling plans. Furthermore, by permitting exemptions to running change testing, the number of manufacturers involved in higher levels of testing will be greatly reduced.

Having examined these alternative methods of sampling manufacturers' product lines, EPA found, as indicated by the preceding discussion, that only the Representative Approach is feasible and meets the criteria set forth previously to an adequate degree. Consequently, this is the approach being promulgated for the 1978 model year and proposed for subsequent model years. Nevertheless, EPA is hereby specifically requesting comments on various aspects of this method of sampling manufacturers' product lines, in addition to general comments on this and other issues involved in this action. Manufacturers are requested to comment on the fuel economy test variability they would anticipate seeing within each of their respective base levels and the components and sources of that variability. Manufacturers are further requested to comment on the testing and cost implications of the recommended plan, e.g., the expected number of required test vehicles and vehicle tests that will have to be provided as a result of this action, the availability of sufficient test capacity, and the costs of complying with these regulations itemized as to such individual costs as vehicle procurement, fuel economy testing and mileage accumulation. Finally, comments are most particularly requested on the enforceability of the standards given a compliance testing program such as that adopted herein, i.e., the acceptability of fuel economy averages derived from such a sampling plan as forming the bases for the assessment of penalties and credits.

VII. 40 CFR PART 36 PROCEDURE CHANGES

A. 1978 Model Year Test Procedure Changes. Effective for the 1978 model year and proposed for 1979 and later model years, the following six amendments are considered relatively straightforward and will provide a more accurate measurement of the fuel economy and exhaust emission levels of the test vehicles. EPA contemplates no adjustment of the emission or fuel economy standards due to these changes as the changes only serve to improve the accuracy of the test measurement or to make the test fuel more representative of commercially available fuel. These changes will have insignificant testing cost impacts.

(1) Quarterly production reports.—The previous requirement for reporting vehicle production on a quarterly basis has yielded information which has not been sufficiently definitive to assess what

vehicle configurations are being produced. The previously required level of definition did not provide production information based on vehicle parameters such as axle ratio, engine and emission control system calibrations, or vehicle car line. Furthermore, the quarterly production report can provide, with some modification, vehicle production information necessary to provide support to emissions and fuel economy related programs and, for the 1978 model year, information required to calculate the manufacturers' average fuel economy values.

The modifications are intended to make the quarterly production reports more useful in supporting both emissions and fuel economy programs (and are essential for calculating manufacturers' averages) with only a single reporting requirement on the manufacturer.

(2) Measure the actual distance traveled.—The actual distance traveled by a vehicle during a test will be measured and used in the calculation of grams/mile and miles/gallon values. Currently, the nominal test cycle distances of 7.5 miles for the city cycle and 10.2 miles for the highway cycle are used. The proposed change is intended to accurately weigh the emission levels and fuel usage by the actual miles traveled rather than by an arbitrarily fixed distance. This change in no way affects the actual performance of the vehicle, but merely measures this performance more accurately.

(3) Increase the Number of Calibration Gases. The number of HC and NOx calibration gases is increased from 2 to 6. This change will improve the confidence in the accuracy with which the progressively lower levels of HC and NOx are measured.

(4) Change the Diesel Fuel Specification. The Diesel fuel specification is being changed to drop the allowable use of No. 1 Diesel fuel which is not commonly available for light duty automotive use. Only No. 2 Diesel fuel will be allowed. No. 2 Diesel fuel is commonly available, has generally been used in past certification programs, and is specified by manufacturers for customer use in all currently marketed Diesels for light duty automotive applications.

(5) Specify Separate Procedures for Cold and Hot Start Failures. Current regulations only specify a single test procedure to be followed should a vehicle fail to easily start during the test. The 1975 Federal Test Procedure includes both a cold start and a hot start. The proposed test procedure change will delineate separate procedures to follow should a vehicle fail to cold start or hot start. The proposed change will apply the present procedure to cold start failure only. A new hot start procedure will be incorporated into the regulations to cover those very infrequent hot start failures. These changes will serve to provide further delineation of procedures which have been followed by EPA and which have commonly been accepted by the automotive industry.

Comments were received from manufacturers regarding ambiguities in the wording used in earlier drafts of this

action relating to the implementation of this change in test procedure. EPA has responded to these concerns and the current language reflects these changes.

(6) Allow Use of Overdrive. The current regulations require that vehicles equipped with overdrive or free-wheeling units be used according to manufacturer's recommendations. The test procedure regulations are hereby being amended so that they no longer disallow the use of overdrive units, but do require that these units be used according to manufacturers' recommendations. In addition, free-wheeling units are no longer required to be locked out of operation. Thus, the regulations will now recognize and give the same credit to the fuel economy benefits of an overdrive unit as is realized in actual use.

B. 1979 and Later Model Year Proposed Changes. Beginning with the 1979 model year (to allow comment and sufficient lead time for implementation), several major test procedure changes are proposed without implementation in 1978. Each of these test procedure changes will provide a more accurate simulation of what the vehicle "sees" during actual on-the-road operation. Although these test procedure changes could be expected to affect exhaust emissions and fuel economy on a specific vehicle, no directional change in either average exhaust emissions or fuel economy is expected when looking at the entire population of vehicles. For example, if all the 1976 model year vehicles currently being sold were tested under both the existing and the proposed test procedures, the average exhaust emission levels and fuel economy would be for all practical purposes the same. Since no necessary or intended directional shift in either exhaust emission or fuel economy will result from these test procedure changes, it will not be necessary to apply a correction factor to the fuel economy test values in order to yield comparable results to the 1975 test procedures as required by the Act.

(1) Use of More Accurate Road Load Simulation. Another change proposed for the 1979 model year is a revised method for setting the dynamometer power absorber. The dynamometer power absorber setting simulates the vehicle road load. This is accomplished by setting the dynamometer power absorber to a value that reflects all major components of total road load of the vehicle: vehicle weight, aerodynamic drag of the vehicle and losses resulting from free-rolling friction of the non-driving tires and wheels. When the vehicle is operated on a dynamometer, the driving tires dissipate more power on the curved roll surface(s) than is dissipated on a flat road surface. This additional power dissipation must be subtracted from vehicle road load to obtain the appropriate dynamometer power absorber setting.

Where twin-roll dynamometers are in use, the additional power dissipated by the driving tires, over and above normal power dissipation on a flat road surface, is assumed to adequately compensate for the power dissipation attributed to non-driving tires and wheels. Therefore, in

calculating the total vehicle road load, the additional power dissipation caused by the curved roll surfaces need not be subtracted. With this assumption the dynamometer power absorber setting represents the aerodynamic drag of the vehicle.

The aerodynamic drag of a vehicle is a function of the vehicle frontal area, body shape, protuberances and other aerodynamic factors. Since the vehicle weight and external size tend to be related, the weight can be used as an indirect predictor of vehicle aerodynamic drag. Vehicle weight is currently used to predict the dynamometer power absorber setting. The functional form of the prediction system is:

$$P = aW^2 + bW + c$$

Where:

P = Dynamometer power absorber setting

W = Vehicle weight

a, b and c are predetermined constants

A relationship such as this, based upon weight only, is satisfactory only so long as most vehicles have about the same weight-to-size correlation that existed when the prediction system was developed. However, the recent emphasis on fuel efficient vehicles has resulted in criticism of this simplified method for selecting the proper dynamometer setting since the manufacturer does not receive credit for aerodynamic improvements. Automobile manufacturers have commented in the past that the flat surface rolling resistance advantage of radial tires is not reflected on the dynamometer. Consequently, criticism has been received that the current dynamometer adjustment procedure does not reflect the fuel economy advantages of radial tires. It should be parenthetically noted that the manufacturers currently have the option of measuring actual road load power and requesting that this empirical value be used to set the dynamometer.

In response to these criticisms and in recognition of the fact that the original data base is already six years old, the EPA conducted a track test program using approximately 70 light-duty vehicles and 15 light-duty trucks. The trucks were tested with various payloads, resulting in a total of approximately 60 light-duty truck tests.

As a result of this test program a system to predict the dynamometer power absorber setting as a function of vehicle weight, frontal area, protuberances and tire type was developed and is being proposed. An equation is proposed for both twin roll dynamometers (with nominal roll diameters of 8-9") and single roll dynamometers (with nominal roll diameters of 48").

Comments on, and data relating to, this proposed approach for determining dynamometer power absorber settings are requested. The data most needed are those relating to tire-road and tire-roll effects. Information and test data are also requested regarding the simulation of air conditioner operation.

(2) *Reduction in Inertia Weight Test Increments.* The second change proposed for the 1979 model year is to reduce the

range of inertia weight test intervals. Currently, the inertia intervals are quite broad, 250 pound intervals for inertia settings up through 2750 pounds, and 500 pound intervals for settings from 3000 to 5500 pounds. Manufacturers argue that even relatively significant weight reductions may go unrewarded, particularly if a vehicle is near the upper end of a class. They also contend that little incentive exists to reduce vehicle weight if they do not receive credit for their action in terms of the testing procedure. On the other hand, relatively minor weight reductions would receive substantial reward if the vehicle were just above the lower end of the class. Manufacturers have every incentive to make these minor changes. Reducing the intervals by half, from 250 to 125 pounds and 500 to 250 pounds would provide incentive for the manufacturers to engage in vehicle weight reduction programs that would result in real fuel economy benefits. This change would also reduce weight-related test errors to 0.4 MPG or less.

Reducing the inertia weight test increments would have a significant impact upon test facilities. Test dynamometers would require physical modifications to allow implementation of smaller inertia weight intervals. This change is proposed for 1979 rather than 1978 because it is doubtful that a sufficient number of dynamometers used by EPA or manufacturers could be modified in time for 1978 model year testing.

One other aspect of this change merits consideration. Currently vehicles are selected to represent the dynamometer inertia intervals. Increasing the number of inertia intervals need not require a corresponding increase in the number of vehicles chosen as test vehicles, but this increase would result if the selection criterion were not revised appropriately. Without revision, the number of test vehicles required may nearly double. The current method of calculating fuel economy values, manufacturers' average values and label values, requires at least one vehicle per inertia weight class. Consideration will be given to revising this such that the number of test vehicles does not increase appreciably and such large increases are not contemplated by these proposals. Interested parties, particularly manufacturers, are invited to comment on this aspect of reducing the inertia weight test increments.

As in the first change, since there is no directional trend to the changes (any given vehicle is just as likely to go into a "heavier" new class as it is likely to go into a "lighter" class) there is no need to adjust the emissions or fuel economy baselevels. This change only serves to more accurately represent the real emission and fuel economy results of the vehicle.

(3) *Definition of option and model, and revision of optional equipment usage.*—The fourth minor change proposed for the 1979 model year includes revisions to emission certification procedures. The current emission regulations lack definitions for model and for option, although both terms are used in

the text of the regulations. The lack of a definition for these terms has led to disagreement between EPA and the manufacturers over the interpretation of the certification requirements. One specific area where controversy exists is that of the manufacturer's product line description. The variety of interpretation of the terms "model" and "option" has led to a lack of consistency in manufacturers' applications for certification. This lack of specificity when referring to "options" may also affect fuel economy values. The current procedure requires that test vehicles include equipment if 33 percent or more of the vehicles in an engine family are projected to be sold with that equipment. This causes many vehicles to be tested at unrepresentative road load and inertia weights, which can result in somewhat unrepresentative fuel economy values.

The definitions proposed for model and option, and the additional related definitions, are intended to clarify the certification requirements and to bring about consistency in the related programs.

The previous certification requirements concerning optional equipment usage as they impacted test vehicle equipment, vehicle inertia weight class and road load air conditioning factor were based on the usage of optional equipment on greater than 33 percent of the engine family. This provision was initially instituted in the 1972 model year regulations as an attempt to more accurately characterize the manufacturer's product lines during testing, on the basis of typical in-use vehicles.

Recently, the engine family basis for definitions relating to optional equipment usage has proven inadequate in making certification vehicles represent in-use vehicles. Some vehicles have been required to be equipped in a manner not typical of in-use vehicles of the same configuration (but typical of vehicles within the engine family).

The proposal to revise the basis for decisions related to optional equipment usage from "engine family" to "car line" should improve the accuracy of the representation of the manufacturers' product lines by their respective test vehicles without having any directional effect on emission or fuel economy results.

(4) *Revise the Fuel Octane Requirements.*—The fuel octane requirements for mileage accumulation and emission testing are being changed to allow use of a lower octane fuel. This change will bring the allowable fuel octane requirements more in line with the fuel commercially available to the consumer and with the minimum octane levels recommended to the purchaser. Thus, this change will allow a more representative assessment of in-use vehicle performance.

VIII. DETERMINATION OF DOMESTIC PRODUCTION

Under certain circumstances, Section 503 of the Act provides that separate fuel economy averages will be calculated for manufacturers' domestic and imported vehicles in cases wherein a manufacturer-

er's product line includes both. This section further provides that the Administrator of EPA may prescribe rules for determining how passenger automobiles will be classified as either foreign or domestic. EPA has found it necessary to define a procedure by which this determination will be made so that all manufacturers will be treated in the same manner and so that manufacturers may plan for future model years in which this determination may become critical to the question of whether or not their domestic production meets the fuel economy standards.

IX. REQUEST FOR COMMENTS

Manufacturers and other interested parties may participate in this rulemaking by submitting comments (in quadruplicate) to the Administrator, Environmental Protection Agency, Attention: Office of Mobile Source Air Pollution Control, 401 M Street, SW., Washington, D.C. 20460. All relevant material received on or before December 9, 1976, will be considered.

A copy of all public comments will be available for inspection and copying at the U.S. Environmental Protection Agency, Public Information Reference Unit, Room 2922 (EPA Library), 401 M Street, SW., Washington, D.C. 20460. As provided in 40 CFR Part 2, a reasonable fee may be charged for copying services.

In accordance with Executive Order 11821 a review of this action was undertaken to determine whether it met the criteria for a "major action" requiring preparation of an Inflationary Impact Statement. The review indicated that the costs and economic impacts of this action are far less than a "major" action and that therefore no IIS is required.

No significant environmental impacts are associated with this action.

X. TITLE AND STATUTORY AUTHORITY

The provisions of this notice pertaining to 40 CFR Part 600 are issued under the authority of Title V of the Motor Vehicle Information and Cost Savings Act, 15 U.S.C. 1901 et seq., as amended by Title III of the Energy Policy and Conservation Act, Pub. L. 94-163, Stat. 901.

The provisions of Part 86 are issued under the authority of sections 202, 206, 207, 208, and 301(a) of the Clean Air Act, as amended (42 U.S.C. 1857f-1, 1857f-5, 1857f-5a, 1857f-6, 1857g(a)).

Parts 86 and 600 of Chapter I, Title 40 of the Code of Federal Regulations are amended, or proposed to be amended as noted above, as follows, effective immediately and applicable as provided herein.

Dated: August 30, 1976

JOHN QUARLES,
Acting Administrator.

Part 86 of Chapter I, Title 40 of the Code of Federal Regulations is amended in Subparts A and B as follows:

1. It is proposed to add § 86.079-2 as follows:

§ 86.079-2 Definitions.

The following definitions apply beginning with the 1979 model year. Section 86.078-2 remains effective.

"Body Style" means a level of commonality in vehicle configuration as defined by number of doors and roof treatment (e.g., Sedan, Convertible, Fastback, Hatchback). Station Wagons and light trucks are identified as separate car lines.

"Drivetrain Configuration" means a unique combination of engine code, transmission configuration and axle ratio.

"Frontal Area" means the area enclosed by the geometrical projection of the vehicle, including tires, onto a plane perpendicular to the longitudinal axis of the vehicle.

"Model" means a specific combination of carline, body style, and drivetrain configuration.

"Option" means any available equipment or feature not standard equipment on a model.

"Public Introduction Date" means that date on which the manufacturer has released for retail sale vehicle configurations whose total projected model year production is estimated to be twenty-five percent or more of his total model year projected production volume.

"Standard Equipment" means those features or equipment which are marketed on a vehicle over which the purchaser can exercise no choice.

2. It is proposed to add a new § 86.079-24 as follows:

§ 86.079-24 Test vehicles and engines.

(a) through (f) inclusive (see paragraphs (a) through (f) of § 86.078-24).

(g) (1) This paragraph applies to light duty vehicles and light duty trucks.

(2) Where it is expected that more than 33 percent of a car line, within an engine-system combination, may be equipped with an item (whether that item is standard equipment or an option), the full estimated weight of that item shall be included in the curb weight computation of each vehicle available with that item in that carline, within that engine-system combination. Where it is expected that 33 percent or less of the carline, within an engine-system combination, will be equipped with an item (whether that item is standard equipment or an option) no weight for that item will be added in computing the curb weight for any vehicle in that carline, within that engine-system combination, unless that item is standard equipment on the vehicle. In the case of mutually exclusive options, only the weight of the heavier option will be added in computing the curb weight. Optional items weighing less than three pounds per item need not be considered.

(3) Where it is expected that more than 33 percent of a car line, within an engine-system combination, will be equipped with an item (whether that item is standard equipment or an option) that can reasonably be expected to influence emissions, then such items shall

actually be installed, unless specifically excluded by the Administrator, on all emission data and durability data vehicles of that car line, within that engine-system combination, on which the items are intended to be offered in production. Items that can reasonably be expected to influence emissions are: air conditioning, power steering, power brakes, and other items determined by the Administrator.

(4) Where it is expected that 33 percent or less of a car line within an engine-system combination, will be equipped with an item (whether that item is standard equipment or an option) that can reasonably be expected to influence emissions, that item shall not be installed on any emission data vehicle or durability data vehicle of that car line, within that engine-system combination, unless that item is standard equipment on that vehicle or specifically required by the Administrator.

3. A new § 86.078-37 is added and reads as follows:

§ 86.078-37 Production vehicles and engines.

(a) (see paragraph (a) of § 86.077-37.)

(b) (1) Any manufacturer of light duty vehicles or light duty trucks, obtaining certification under this part shall notify the Administrator, on a quarterly basis, of the number of vehicles domestically produced for sale in the United States and the number of vehicles produced and imported for sale in the United States during the preceding quarter. A manufacturer may elect to provide this information every 60 days instead of quarterly, to combine it with the notification required under § 86.077-36. The notification must be submitted 30 days after the close of the reporting period. The vehicle production information required shall be submitted as follows:

(i) Total production volume expressed in terms of units produced.

(ii) Model type production volume, expressed for each model type in terms of units produced and as a percentage of total production.

(iii) Base level production volume, expressed for each base level in terms of units produced and as a percentage of (A) the total production of its respective model type(s) and, (B) total production.

(iv) Vehicle configuration production volume, expressed for each vehicle configuration in terms of units produced, and as a percentage of the total production of its respective base level. In addition, each vehicle configuration shall be identified by its appropriate engine-system combination.

(2) [See paragraph (b) (2) of § 86.077-37]

(c) [See paragraph (c) of § 86.077-37]

(d) The following definitions apply to this section:

(1) "Model Type" means a unique combination of car line, basic engine, and transmission class.

(2) "Base Level" means a unique combination of basic engine, inertia weight, and transmission class.

4. It is proposed to add a new section, § 86.113-79, to read as follows:

§ 86.113-79 Fuel specifications.

(a) Gasoline. (1) Gasoline having the following specifications will be used by the Administrator in exhaust and evaporative emission testing. Gasoline having the following specifications or substantially equivalent specifications approved by the Administrator, shall be used by the manufacturer in exhaust and evaporative testing, except that the lead and octane specifications do not apply.

Item	ASTM	Leaded	Unleaded
Octane, research, minimum	D2699	98	93
Sensitivity, minimum		9.0	7.5
Lead (organic), grams/U.S. gallon		1.4	0.00-0.05
Distillation range:			
IBP, °F	D86	75-95	75-95
10 pct point, °F	D86	120-135	120-135
50 pct point, °F	D86	200-230	200-230
90 pct point, °F	D86	300-325	300-325
EP, °F (maximum)	D86	415	415
Sulphur, weight percent, maximum	D1266	0.10	0.10
Phosphorus, grams/U.S. gallon, maximum		0.01	0.005
RVP, pounds per square inch	D323	8.7-9.2	8.7-9.2
Hydrocarbon composition:			
Olefins, percent, maximum	D1319	10	10
Aromatics, percent maximum	D1319	35	35
Saturates	D1319	(c)	(c)

¹ Minimum.

² For testing at altitudes above 1,219 m (4,000 ft) the specified range is 75-105.

³ For testing which is unrelated to evaporative emission control, the specified range is 8.0-9.2.

⁴ For testing at altitudes above 1,219 m (4,000 ft) the specified range is 7.9-9.2.

⁵ Remainder.

(2) Gasoline representative of commercial gasoline which will be generally available through retail outlets shall be used in service accumulation. For leaded gasoline the minimum lead content shall be 1.4 grams per U.S. gallon, except that where the Administrator determines that vehicles represented by a test vehicle will be operated using gasoline of different lead content than that prescribed in this paragraph, he may consent in writing to use a gasoline with a different lead content. The octane rating of the gasoline used shall be no higher than 1.0 research octane number above the minimum recommended by the manufacturer and have a minimum sensitivity of 8.0 octane numbers, where sensitivity is defined as the Research octane number minus the Motor octane number. The Reid Vapor Pressure of the gasoline used shall be characteristic of the motor fuel used during the season in which the service accumulation takes place.

(3) The specification range of the gasoline to be used under paragraph (a) (2) of this section shall be reported in accordance with § 86.077-21(b) (3).

§ 86.113-78 [Amended]

5. § 86.113-78 is amended by revising the last sentence of the text and the table in paragraph (b) (2), and revising the last sentence of the text and the table in paragraph (b) (3) as follows:

(b) * * *

(2) * * * "Type 2D" grade diesel fuel shall be used.

(3) * * * "Type 2-D" grade diesel fuel shall be used.

Item	ASTM test method No.	Type 2-D
Cetane (minimum)	D613	38-58
Distillation range:		
90 percent point, °F	D86	430-630
Gravity °API	D237	30-42
Total sulfur, percent (minimum)	D129 or D2622	0.2
Flashpoint, °F (minimum)	D93	130
Viscosity, centistokes	D455	1.5-4.5

6. § 86.114-78 is amended by adding paragraph (a) (7) to read as follows:

§ 86.114-78 Analytical gases.

(a) * * *

(7) The use of proportioning and precision blending devices to obtain the re-

quired analyzer gas concentrations is allowable provided their use has been approved in advance by the Administrator.

7. § 86.121-78 is amended by revising paragraph (b) (3) to read as follows:

§ 86.121-78 Hydrocarbon analyzer calibration.

(b) * * *

(3) Calibrate on each normally used operating range with propane in air calibration gases having nominal concentrations of 15, 30, 45, 60, 75, and 90 percent of that range. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

8. § 86.123-78 is amended by revising paragraph (b) (3) to read as follows:

§ 86.123-78 Oxides of nitrogen analyzer calibration.

(b) * * *

(3) Calibrate on each normally used operating range with NO in N₂ calibration gases having nominal concentrations of 15, 30, 45, 60, 75, and 90 percent of that range. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

9. It is proposed to add a new section, § 86.129-79, to read as follows:

§ 86.129-79 Dynamometer Adjustment To Stimulate Vehicle Inertia and Road Load.

(a) Flywheels, electrical or other means of simulating inertia as shown in the following table be used.

(1) Light duty vehicles.

Loaded vehicle weight (pounds)	Equivalent inertia weight (pounds)
Up to 1,062	1,000
1,063 to 1,187	1,125
1,188 to 1,312	1,250
1,313 to 1,437	1,375
1,438 to 1,562	1,500

Loaded vehicle weight (pounds)	Equivalent inertia weight (pounds)
1,563 to 1,687	1,625
1,688 to 1,812	1,750
1,813 to 1,937	1,875
1,938 to 2,062	2,000
2,063 to 2,187	2,125
2,188 to 2,312	2,250
2,313 to 2,437	2,375
2,438 to 2,562	2,500
2,563 to 2,687	2,625
2,688 to 2,812	2,750
2,813 to 2,937	2,875
2,938 to 3,062	3,000
3,063 to 3,187	3,125
3,188 to 3,312	3,250
3,313 to 3,437	3,375
3,438 to 3,562	3,500
3,563 to 3,687	3,625
3,688 to 3,812	3,750
3,813 to 3,937	3,875
3,938 to 4,125	4,000
4,126 to 4,375	4,250
4,376 to 4,625	4,500
4,626 to 4,875	4,750
4,876 to 5,125	5,000
5,126 to 5,375	5,250
5,376 to above	5,500

(2) **Light duty trucks.** The table in paragraph (a) (1) of this section shall apply to light duty trucks with loaded vehicle weights below 5,375 lbs. Above 5,375 lbs, the following table shall apply:

Loaded vehicle weight (pounds)	Equivalent inertia weight (pounds)
5376 to 5750	5,500
5751 to 6250	6,000
6251 to 6750	6,500
6751 to 7250	7,000
7251 to 7750	7,500
7751 to 8250	8,000
8251 to 8750	8,500
8751 to 9250	9,000
9251 to 9750	9,500
9751 to 10,000	10,000

(b) **Power absorption unit adjustment.**

(1) The power absorption unit shall be adjusted to reproduce road load power at 50 mph true speed. The indicated road load power setting shall take into account the dynamometer friction. The relationship between road load (absorbed) power and indicated road load power for a particular dynamometer shall be determined by the procedure outlined in § 86.118 or other suitable means.

(2) The dynamometer road load setting is determined from the equivalent inertia weight, the frontal area, the body shape, the vehicle protuberances and the tire type by the following equations. Alternately, the vehicle road load may be determined by a procedure proposed by the manufacturer and approved in advance by the Administrator.

(i) For light duty vehicles to be tested on a twin roll dynamometer (with nominal roll size of 8.65" and 17" nominal roll spacing⁶).

$$Hp = 2.48 + 4.78 \times 10^{-4} A + 1.73 \times 10^{-2} AS + 1.56P + 2.17 \times 10^{-1} TW$$

⁶ NOTE.—Dynamometers with roll specifications other than those shown may be used if the road load power settings can be shown to be equivalent and if approved in advance by the Administrator.

where:

Hp = the dynamometer power absorber setting at 50 mph (horsepower)
 A = vehicle frontal area (ft.²)
 S = vehicle shape factor (dimensionless)
 P = vehicle protuberance factor (dimensionless)
 T = tire type (0 for bias ply tires, -1 for radial ply)
 W = vehicle equivalent inertia weight (lbs.) from the table in paragraph (a)

(A) The vehicle shape factor is given by:

$$S = \sum_{i=1}^6 a_i s_i$$

where the a_i weighting factors are:

$a_1 = 2$
 $a_2 = 1$
 $a_3 = 1$
 $a_4 = 1$
 $a_5 = 1$
 $a_6 = 2$

and the s_i are defined in the following paragraphs.

(1) The shape factors consider the front deck of the vehicle, the rear deck, the front, rear and side surfaces and the transitions from these surfaces to the other vehicle surfaces. The front deck is defined as the horizontal or inclined surface extending forward from the foremost point of the windshield. The rear deck is defined to include all horizontal or inclined surfaces extending rearward from the rearmost point of the windshield. The front surface of the vehicle is defined as the vertical or nearly vertical surface at the front of the vehicle. The vehicle side surface is defined as the vertical or nearly vertical surface in a frontal view of the vehicle.

(2) The term s_1 describes the longitudinal sections of the front deck of the vehicle and their transition into the front surface (side view of the vehicle front deck).

$s_1 = -1$ for those vehicles where the projected area of the front deck of the vehicle, which is inclined less than 30° from the horizontal, is at least 33% of the projected frontal area of the vehicle below the windshield-body transition.

$s_1 = -1$ for those vehicles where the transition from the front deck to the front surface has a radius of curvature greater than 8" in all longitudinal sections. (The curvature must subtend an angle greater than or equal to one radian to be considered.)

$s_1 = 0$ for those vehicles not satisfying the $s_1 = -1$ criteria, but where the transition from the front deck to the front surface has a radius of curvature greater than 4" but less than or equal to 8" in all longitudinal sections. (The curvature must subtend an angle of greater than or equal to one radian to be considered.)

$s_1 = +1$ for all other vehicles.

(3) The term s_2 describes the transition between the vehicle front and side surfaces through horizontal sections. (Top view of the vehicle front surface.)

$s_2 = -1$ for those vehicles where the transition has a radius of curvature greater than 8" in all horizontal sections. In addition there can be no protuberances on this surface.

$s_2 = 0$ for those vehicles where the transition has a radius of curvature greater than 4" but less than 8" in all horizontal sections. In addition, there can be no protuberances on this surface.

$s_2 = +1$ for all other vehicles.

(4) The term s_3 describes the windshield surface, and the transition of this surface to the vehicle side surface through horizontal sections. (Top view.)

$s_3 = -1$ for those vehicles where the radius of curvature of the transition from the center of the windshield to the side surface of the vehicle is greater than 8".

$s_3 = 0$ for those vehicles where the radius of curvature of the transition from the center of the windshield to the side of the vehicle is greater than 4" but less than or equal to 8".

$s_3 = +1$ for all other vehicles.

(5) The term s_4 describes the angle of inclination (from horizontal) of the windshield at the centerline.

$s_4 = -1$ for vehicles where the angle of inclination is less than 30° from horizontal.

$s_4 = 0$ for vehicles where the angle of inclination is less than 60° but greater than or equal to 30° from horizontal.

$s_4 = +1$ for vehicles not satisfying either of the above criteria.

(6) The term s_5 describes the transition of the side surface to the rear surface through horizontal sections. (Top view of the vehicle rear.)

$s_5 = -1$ for those vehicles where at least 33% of the rear projected area of the vehicle have lines of intersection with horizontal longitudinal planes which form an angle of less than 20° from the longitudinal axis of the vehicle.

$s_5 = 0$ for those vehicles where at least 20% but less than 33% of the rear projected area of the vehicle have lines of intersection with horizontal longitudinal planes which form an angle of less than 20° with the longitudinal axis of the vehicle.

$s_5 = +1$ for all other vehicles.

(7) The term s_6 describes the longitudinal sections of the rear deck of the vehicle and their transition into the rear surface. (Side view of the vehicle rear deck.)

$s_6 = -2$ for those vehicles where greater than 50% of the projected rear area of the vehicle have lines of intersection with vertical longitudinal section planes which are inclined less than 20° from the horizontal.

$s_6 = -1$ for those vehicles where greater than 33% but less than or equal to 50% of the projected rear area of the vehicle has lines of intersection with vertical longitudinal section planes which are inclined less than 20° from the horizontal.

$s_6 = 0$ for those vehicles where greater than 33% of the projected rear area of the vehicle has lines of intersection with vertical longitudinal section planes which are inclined less than 45° from the horizontal.

$s_6 = +1$ for those vehicles not satisfying the $s_6 = -2$, $s_6 = -1$ or $s_6 = 0$ criteria, but which have closed rear surfaces.

$s_6 = +2$ for those vehicles with an open rear surface, (such as a pick-up bed).

(B) the protuberance factor is given by:

$$P = \sum_{i=1}^7 b_i p_i$$

where the weighting factors b_i are:

$b_1 = 1.00$
 $b_2 = 0.200$
 $b_3 = 0.091$
 $b_4 = 0.215$
 $b_5 = 0.250$
 $b_6 = 0.250$
 $b_7 = 0.500$

The protuberance terms are:

$P_1 = 1$ if the vehicle is equipped with a roof rack

P_2 = the number of protruding external aerials

P_3 = the number of hood ornaments protruding more than 0.375 inch from the hood surface

P_4 = the number of mirrors on the vehicle which are not located directly in the vehicle air stream, having aerodynamic shapes (where the longitudinal dimension exceeds the maximum transverse dimension).

P_5 = the number of mirrors on the vehicle, not directly located in the vehicle air stream, but which do not meet the dimensional criterion of P_4 .

P_6 = the number of mirrors on the vehicle which are located in the vehicle air stream, having aerodynamic shapes (where the maximum longitudinal dimension exceeds the maximum transverse dimension).

p_7 = the number of mirrors on the vehicle not meeting the criteria of P_1 , P_5 , or P_6

(1) Protuberance terms p_1 , p_2 , & p_3 shall be zero if the vehicle is not equipped with such items. For protuberance terms p_4 through p_7 , a mirror shall be considered in the vehicle air stream unless it is entirely behind the projection of the windshield surface and within 8" of the vehicle side.

(ii) For light duty vehicles to be tested on a single, large roll dynamometer (with nominal roll diameter of 48 inches*):

$$H_p = 2.48 + 4.78 \times 10^{-4} A + 1.73 \times 10^{-2} AS + 1.56P + (6.13 \times 10^{-4} + 1.08 \times 10^{-4} T)W$$

All symbols in the above equation are defined in paragraph (b) (2) (i) of this section.

(iii) For light duty trucks to be tested on a twin roll dynamometer (with nominal roll size 3.65" and 17" nominal spacing*):

$$H_p = 2.48 + 4.78 \times 10^{-4} A + 1.73 \times 10^{-2} AS + 1.56P + 2.17 \times 10^{-4} TW$$

All symbols in the above equation are defined in paragraph (b) (2) (i) of this section.

(iv) For light duty trucks to be tested on a single, large roll dynamometer (with nominal roll diameter of 48 inches*):

$$H_p = 2.48 + 4.78 \times 10^{-4} A + 1.73 \times 10^{-2} AS + 1.56P + (6.13 \times 10^{-4} + 1.08 \times 10^{-4} T)W$$

All symbols in the above equation are defined in paragraph (b) (2) (i).

(v) If vehicles exist within a car line within an engine-system combination with different shapes and protuberance factors, these factors shall be chosen such that less than 33% of the vehicles sold have a higher actual or expected road load than the value resulting from the methodology contained in this paragraph using the selected shape and protuberance factors.

(3) Where it is expected that more than 33 percent of a car line within an engine-system combination will be equipped with air conditioning, per § 86.078-24(g) (2), the road load power as determined in paragraph (b) (2) of this section shall be increased by 10 percent for testing all test vehicles of that car line within that engine-system combination if those vehicles are intended to be offered with air conditioning in production.

10. § 86.135-78 is amended by adding paragraph (h) to read as follows:

§ 86.135-78 Dynamometer procedure.

(h) The driving distance as measured by counting the number of dynamometer roll or shaft revolutions, shall be determined for the transient cold start, stabilized cold start, and transient hot start phases of the test. The revolutions shall be measured on the same roll or shaft used for measuring the vehicle's speed.

11. § 86.136-78 is amended by revising paragraph (c) to read as follows:

§ 86.136-78 Engine starting and re-starting.

(c) If the vehicle does not start after 10 seconds of cranking, cranking shall cease and the reason for failure to start shall be determined. The gas flow measuring device (or revolution counter) on the constant volume sampler (and the

* Dynamometers with roll specifications other than those shown may be used if the road load power settings can be shown to be equivalent and if approved in advance by the Administrator.

hydrocarbon integrator when testing diesel vehicles, see § 85.135 Dynamometer Test Runs) shall be turned off and the sample selector valves placed in the "standby" position during this diagnostic period. In addition, either the CVS should be turned off or the exhaust tube disconnected from the tailpipe during the diagnostic period. If failure to start is an operational error, the vehicle shall be rescheduled for testing from a cold start.

(1) If a failure to start occurs during the cold portion of the test and is caused by a vehicle malfunction corrective action of less than 30 minutes duration may be taken (according to § 86.077-25), and the test continued. The sampling system shall be reactivated at the same time cranking begins. When the engine starts, the driving schedule timing sequence shall begin. If failure to start is caused by vehicle malfunction and the vehicle cannot be started, the test shall be voided, the vehicle removed from the dynamometer, and corrective action may be taken according to § 86.077-25. The reasons for the malfunction (if determined) and the corrective action taken shall be reported.

(2) If a failure to start occurs during the hot start portion of the test and is caused by vehicle malfunction, the vehicle must be started within one minute of key on. The sampling system shall be reactivated at the same time cranking begins. When the engine starts, the driving schedule timing sequence shall begin. If the vehicle cannot be started within one minute of key on, the test shall be voided, the vehicle removed from the dynamometer, corrective action taken, (according to § 86.077-25), and the vehicle rescheduled for testing. The reason for the malfunction (if determined) and the corrective action taken shall be reported.

12. § 86.137-78 is amended by adding a second sentence to paragraph (b) (1), revising paragraph (b) (7), inserting a sentence after the first sentence of paragraph (b) (11), inserting a sentence after the first sentence of paragraph (b) (13), revising the second sentence of paragraph (b) (16), and adding a sentence at the end of paragraph (b) (17). § 86.137-78 is amended to read as follows:

§ 86.137-78 Dynamometer test runs.

(1) * * * Reset and enable the roll revolution counter.

(7) Start the gas flow measuring device, position the sample selector valves to direct the sample flow into the "transient" exhaust sample bag and the "transient" dilution air sample bag (turn on the diesel hydrocarbon analyzer system integrator and mark the recorder chart, if applicable), turn the key on, and start cranking the engine.

(11) * * * Before the acceleration which is scheduled to occur at 510 seconds, record the measured roll or shaft

revolutions and reset the counter or switch to a second counter. * * *

(13) * * * Record the measured roll or shaft revolutions and reset the counter. * * *

(16) * * * The key-on operation step described in paragraph (b) (7) of this section shall begin between 9 and 11 minutes after the end of the sample period for the cold start test.

(17) * * * Record the measured roll or shaft revolutions.

13. § 86.142-78 is amended by revising paragraph (f) and adding paragraph (p) to read as follows:

§ 86.142-78 Records required.

(f) Vehicle: ID number, Manufacturer, Model year, Standards, Engine family, Evaporative emissions family, Basic engine description (including displacement, number of cylinders, and catalysts usage), Fuel system (including number of carburetors, number of carburetor barrels, fuel injection type, and fuel tank(s) capacity and location), Engine code, Inertia weight class, Actual curb weight at zero miles, Actual road load at 50 mph, Transmission configuration, Axle ratio, Car line, Odometer reading, Idle rpm and Drive wheel tire pressure, as applicable.

(p) The driving distance for each of the three phases of the test, calculated from the measured roll of shaft revolutions.

14. Section 86.144-78 is amended by revising paragraph (a); adding two terms to the end of the text portion of paragraph (d) (1), revising the equation for humidity and adding two equations to the end of paragraph (d) (1); adding two equations to the end of paragraph (d) (2); adding two equations to the end of paragraph (d) (3); and revising paragraph (d) (4). § 86.144-78 is amended to read as follows:

§ 86.144-78 Calculations; exhaust emissions.

The final reported test results shall be computed by use of the following formula:

(a) For light duty vehicles and light duty trucks:

$$Y_{wm} = 0.43 ((Y_{et} + Y_s) / (D_{et} + D_s)) + 0.57 ((Y_{ht} + Y_s) / (D_{ht} + D_s))$$

Where:

Y_{wm} = Weighted mass emissions of each pollutant, i.e., HC, CO, NO_x or CO₂, in grams per vehicle mile.

Y_{et} = Mass emissions as calculated from the "transient" phase of the cold start test, in grams per test phase.

Y_{ht} = Mass emissions as calculated from the "transient" phase of the hot start test, in grams per test phase.

Y_s = Mass emissions as calculated from the "stabilized" phase of the cold start test, in grams per test phase.

D_{et} = The measured driving distance from the "transient" phase of the cold start test, in miles.

D_{ht} = The measured driving distance from the "transient" phase of the hot start test, in miles.

D_s = The measured driving distance from the "stabilized" phase of the cold start test, in miles.

(d) * * *

(1) * * * $CO_{M} = 0.032\%$; $D_{M} = 3.598$ miles.

$H = (43.478) (48.2) (22.225) / [762 - (22.225 \times 48.2 / 100)] = 62$
grains of water per pound of dry air.

$CO_{Tonic} = 1.43 - .032 (1 - 1/9.116) = 1.402\%$
 $CO_{Tonic} = (2595.0) (51.85) (1.402/100)$
 $= 1886$ grams per test phase.

(2) * * *

$CO_{Tonic} = 2346$ grams per test phase.
 $D_{M} = 3.902$ miles.

(3) * * *

$CO_{Tonic} = 1758$ grams per test phase.
 $D_{M} = 3.598$ miles.

(4) Weighted mass emission results:

$HC_{wm} = 0.43 [(4.027 + 0.62) / (3.598 + 3.902)] + 0.57 [(0.51 + 0.62) / (3.598 + 3.902)] = 0.352$ grams per vehicle mile.
 $NO_{wm} = 0.43 [(1.389 + 1.27) / (3.598 + 3.902)] + 0.57 [(1.38 + 1.27) / (3.598 + 3.902)] = 0.354$ grams per vehicle mile.
 $CO_{wm} = 0.43 [(23.96 + 5.98) / (3.598 + 3.902)] + 0.57 [(5.01 + 5.98) / (3.598 + 3.902)] = 2.55$ grams per vehicle mile.
 $CO_{2wm} = 0.43 [(1886 + 2346) / (3.598 + 3.902)] + 0.57 [(1758 + 2346) / (3.598 + 3.902)] = 555$ grams per vehicle mile.

Sec. 202, 206, 207, 208 and 301(a) of the Clean Air Act, as amended (42 U.S.C. 1857f-1, 1857f-5, 1857f-5a, 1857f-6, 1857g(a)).

15. 40 CFR Part 600 is added as follows:

Subpart A—Fuel Economy Regulations for 1977 and Later Model Year Automobiles—General Provisions

- Sec.
600.001-77 General applicability.
600.002-77 Definitions.
600.003-77 Abbreviations.
600.004-77 Section numbering, construction.
600.005-77 [Reserved]
600.006-77 Data to be submitted.
600.007-77 Vehicle acceptability.
600.008-77 Review of fuel economy data, testing by the Administrator.
600.009-77 Hearings on acceptance of test data.

Subpart B—Fuel Economy Regulations for 1978 and Later Model Year Automobiles—Test Procedures

- 600.101-78 General applicability.
600.102-78 Definitions.
600.103-78 Abbreviations.
600.104-78 Section numbering, construction.
600.105-78 Record keeping.
600.106-78 Equipment requirements.
600.107-78 Fuel specifications.
600.108-78 Analytical gases.
600.109-78 EPA driving cycles.
600.110-78 Equipment calibration.
600.111-78 Test procedures.
600.112-78 Exhaust sample analysis.
600.113-78 Fuel economy calculations.

Subpart C—Fuel Economy Regulations for 1977 and Later Model Year Automobiles—Procedures for Calculating Fuel Economy Values

- 600.201-77 General applicability.
600.202-77 Definitions.
600.203-77 Abbreviations.
600.204-77 Section numbering, construction.
600.205-77 Record keeping.
600.206-77 Calculation and use of fuel economy values for a vehicle configuration.
600.207-77 Calculation and use of fuel economy values for a model type.

Subpart D [Reserved]

Subpart E [Reserved]

Subpart F—Fuel Economy Regulations for 1978 and Later Model Year Automobiles—Procedures for Determining Manufacturer's Average Fuel Economy

- 600.501-78 General applicability.
600.502-78 Definitions.
600.503-78 Abbreviations.
600.504-78 Section numbering, construction.
600.505-78 Record keeping.
600.506-78 Preliminary determination of manufacturer's average.
600.507-78 Running change data requirements.
600.508-78 Addition of a base level-data requirements.
600.509-78 Voluntary submission of additional data.
600.510-78 Determination of average fuel economy.
600.511-78 Determination of domestic production.
600.511-80 Determination of domestic production.
600.512-78 Independent audit of production data.

Appendix I—Highway Fuel Economy Driving Schedule.

Appendix II—Sample Test Value Calculation.

AUTHORITY: Title V of the Motor Vehicle Information and Cost Savings Act (15 U.S.C. 1901 et seq.) as amended by Title III of the Energy Policy and Conservation Act, Pub. L. 94-163, 89 Stat. 871.

Subpart A—Fuel Economy Regulations for 1977 and Later Model Year Automobiles—General Provisions

§ 600.001-77 General applicability.

The provisions of this subpart are applicable to 1977 and later model year automobiles. The requirements apply to all automobiles of the respective model year regardless of the date of production.

§ 600.002-77 Definitions.

(a) As used in this subpart all terms not defined herein shall have the meaning given them in the Act:

(1) "Act" means Part I of Title V of the Motor Vehicle Information and Cost Savings Act (15 U.S.C. 1901 et seq.).

(2) "Administrator" means the Administrator of the Environmental Protection Agency or his authorized representative.

(3) "Secretary" means the Secretary of Transportation or his authorized representative.

(4) "Automobile" means any 4-wheeled vehicle propelled by fuel which is manufactured primarily for use on public streets, roads, or highways (except any vehicle operated on a rail or rails) and which is rated at 6,000 lbs gross vehicle weight or less or is a type of vehicle which the Secretary determines is substantially used for the same purposes.

(5) "Passenger Automobile" means any automobile which the Secretary determines is manufactured primarily for use in the transportation of no more than 10 individuals.

(6) "Model Year" means the manufacturer's annual production period (as determined by the Administrator) which includes January 1 of such calendar year.

If a manufacturer has no annual production period, the term "model year" means the calendar year.

(7) "Federal Emission Test Procedure" refers to the dynamometer driving schedule, dynamometer procedure, and sampling and analytical procedures described in Part 86 for the respective model year, which are used to derive city fuel economy data.

(8) "Federal Highway Fuel Economy Test Procedure" refers to the dynamometer driving schedule, dynamometer procedure, and sampling and analytical procedures described in Subpart B of this part and which are used to derive highway fuel economy data.

(9) "Fuel" means gasoline and diesel fuel.

(10) "Fuel Economy" means the average number of miles traveled by an automobile or group of automobiles per gallon of gasoline or diesel fuel consumed as computed in § 600.113 or § 600.207.

(11) "City Fuel Economy" means the fuel economy determined by operating a vehicle (or vehicles) over the driving schedule in the Federal Emission Test Procedure.

(12) "Highway Fuel Economy" means the fuel economy determined by operating a vehicle (or vehicles) over the driving schedule in the Federal Highway Fuel Economy Test Procedure.

(13) "Combined Fuel Economy" means the fuel economy value determined for a vehicle (or vehicles) by harmonically averaging the city and highway fuel economy values, weighted 0.55 and 0.45 respectively.

(14) "Average Fuel Economy" means the production-weighted combined fuel economy value of all passenger automobiles produced by a manufacturer in a single model year as computed in § 600.510.

(15) "Certification Vehicle" means a vehicle which is selected under § 86.077-24(b) and used to determine compliance under § 86.077-30 for issuance of an original certificate of conformity.

(16) "Fuel Economy Data Vehicle" means a vehicle used for the purpose of determining fuel economy which is not a certification vehicle.

(17) "Label" means a sticker that contains fuel economy information and is affixed to new automobiles in accordance with Subpart D of this part.

(18) "Dealer" means a person who resides or is located in the United States, any territory of the United States or the District of Columbia and who is engaged in the sale or distribution of new automobiles to the ultimate purchaser.

(19) "Model Type" means a unique combination of car line, basic engine, and transmission class.

(20) "Car Line" means a name denoting a group of vehicles within a make or car division which has a degree of commonality in construction (e.g., body, chassis.) Car line does not consider any level of decor or opulence and is not gen-

erally distinguished by characteristics as roof line, number of doors, seats or windows except for station wagons or light-duty trucks. Station wagons and light-duty trucks are considered to be different car lines than passenger cars.

(21) "Basic Engine" means a unique combination of manufacturer, engine displacement, number of cylinders, fuel system (as distinguished by number of carburetor barrels or use of fuel injection), catalyst usage, and other engine and emission control system characteristics specified by the Administrator.

(22) "Transmission Class" means the basic type of transmission, e.g., manual, automatic or semi-automatic.

(23) "Base Level" means a unique combination of basic engine, inertia weight, and transmission class.

(24) "Vehicle Configuration" means a unique combination of basic engine, engine code, inertia weight, transmission configuration, and axle ratio within a base level.

(25) "Engine Code" means a unique combination, within an engine-system combination (as defined in Part 86), of displacement, carburetor (or fuel injection) calibration, distributor calibration, choke calibration, auxiliary emission control devices and other engine and emission control system components specified by the Administrator.

(26) "Inertia Weight" means the inertia weight class into which a vehicle is grouped based on its loaded vehicle weight in accordance with the provisions of Part 86.

(27) "Transmission Configuration" means a unique combination, within a transmission class, of the number of forward gears, and, if applicable, overdrive. The Administrator may further subdivide a transmission configuration (based on such criteria as gear ratios, torque converter multiplication ratio, stall speed, shift calibration, etc.) if he determines that significant fuel economy differences exist within that transmission configuration.

(28) "Axle Ratio" means the number of times the input shaft to the differential (or equivalent) turns for each turn of the drive wheels.

(29) "Auxiliary Emission Control Devices (AECD)" means an element of design as defined in Part 86.

(30) "Rounded" means a number shortened to the specific number of decimal places in accordance with the "Round Off Method" specified in ASTM E 29-67.

(31) "Calibration" means the set of specifications, including tolerances, unique to a particular design, version or application of a component or component assembly capable of functionally describing its operation over its working range.

(32) "Production Volume" means, for a domestic manufacturer, the number of vehicle units domestically produced in a particular model year but not exported, and for a foreign manufacturer, means the number of vehicle units of a particular model imported into the United States.

§ 600.003-77 Abbreviations.

(a) The abbreviations used in this subpart have the same meaning as those in 40 CFR Part 86, with the addition of the following: "MPG" means miles per gallon.

§ 600.004-77 Section numbering, construction.

The model year of initial applicability is indicated by the section number. The two digits following the hyphen designate the first model year for which a section is effective. A section is effective until superseded.

EXAMPLE: Section 600.111-78 applies to the 1978 and subsequent model years until superseded. If a section 600.111-81 is promulgated it would take effect beginning with the 1981 model year; § 600.111-78 would apply to model years 1978 through 1980.

§ 600.005-77 [Reserved]

§ 600.006-77 Data to be submitted.

(a) For certification vehicles the requirements of this section are considered to have been met.

(b) The manufacturer shall submit the following information for each fuel economy data vehicle:

(1) A description of the vehicle, exhaust emission test results, applicable deterioration factors, and adjusted exhaust emission levels.

(2) A statement of the origin of the vehicle including total mileage, mode of mileage accumulation, and modifications (if any) from the vehicle configuration in which the mileage was accumulated. (For modifications requiring advance approval by the Administrator, the name of the Administrator's representative approving the modification and date of approval are required.) If the vehicle was previously used for testing for compliance with Part 86 of this chapter or previously accepted by the Administrator as a fuel economy data vehicle in a different configuration, the requirements of this subparagraph may be satisfied by reference to the vehicle number and previous configuration.

(3) A description of all maintenance to engine, emission control system or fuel system components performed within 2000 miles prior to fuel economy testing.

(4) A copy of calibrations for engine, fuel system, and emission control devices, showing the calibration of the actual components on the test vehicle as well as the design tolerances. (If calibrations for components were submitted previously as part of the description of another vehicle or configuration, the original submittal may be referenced.)

(5) A statement that the fuel economy data vehicle, with respect to which data are submitted:

(i) Has been tested in accordance with applicable test procedures,

(ii) Is, to the best of the manufacturer's knowledge, representative of the vehicle configuration listed, and

(iii) Is in compliance with applicable exhaust emission standards.

(c) The manufacturer shall submit the following fuel economy data:

(1) For each fuel economy data vehicle: all individual test results, including results of invalid and zero mile tests, and the harmonic average of all city fuel economy tests (except the results of invalid or zero mile tests) and the harmonic average fuel economy of all highway fuel economy tests (except the results of invalid or zero mile tests), conducted by the manufacturer.

(2) For a certification vehicle, as defined in this part and tested by the Administrator under Part 86 of this chapter: the city and highway fuel economy results from the test or tests on that vehicle.

(d) The manufacturer shall submit an indication of the intended purpose of the data (e.g., data required by the general labeling program or voluntarily submitted for specific labeling, etc.).

(e) In lieu of submitting actual data from a test vehicle, a manufacturer may provide fuel economy values derived from an analytical expression, e.g., regression analysis. In order for fuel economy values derived from analytical methods to be accepted, the expression (form and coefficients) must have been approved by the Administrator.

(f) If in conducting tests required or authorized by this part the manufacturer utilizes procedures, equipment, or facilities not described in the Application for Certification required in § 86.077-21, the manufacturer shall submit a description of such procedures, equipment, and facilities.

§ 600.007-77 Vehicle acceptability.

(a) All certification vehicles and other vehicles tested to meet the requirements of Part 86 (other than those chosen per § 86.077-24(c)) are considered to have met the requirements of this section.

(b) Any vehicle not meeting the provisions of paragraph (a) must be judged acceptable by the Administrator under this section in order for the test results to be reviewed for use in Subpart C or F of this part. The Administrator will judge the acceptability of a fuel economy data vehicle on the basis of the information supplied by the manufacturer under § 600.006(b). The criteria to be met are:

(1) A fuel economy data vehicle may have accumulated not more than 10,000 miles. This requirement will be considered to have been met if the base vehicle (i.e., chassis and basic engine) has accumulated 10,000 or fewer miles. Components other than engine, emission control system, and drivetrain are not required to be the same components installed when the mileage was accumulated.

(2) A vehicle may be tested in different vehicle configurations by change of vehicle components, as specified in paragraph (b)(1), or by testing at different inertia weights or road load power settings. For the purpose of this part, each vehicle configuration will be considered a distinct vehicle and must be identified accordingly.

(3) The mileage on a fuel economy data vehicle must be, to the extent pos-

sible, accumulated according to § 86.077-26(a) (2).

(4) Each fuel economy data vehicle must meet the same exhaust emission standards as certification vehicles of the respective engine-system combination during the test in which the city fuel economy test results are generated. The deterioration factors established for the respective engine-system combination per § 86.077-28 will be used.

(5) The calibration information submitted under § 600.006(b) must be representative of the vehicle configuration for which the fuel economy data were submitted.

(c) If, based on review of the information submitted under § 600.006(b), the Administrator determines that a fuel economy data vehicle meets the requirements of this section, the fuel economy data vehicle will be judged to be acceptable and fuel economy data from that fuel economy data vehicle will be reviewed pursuant to § 600.008.

(d) If, based on the review of the information submitted under § 600.006(b), the Administrator determines that a fuel economy data vehicle does not meet the requirements of this section, the Administrator will reject that fuel economy data vehicle and inform the manufacturer of the rejection in writing.

§ 600.008-77 Review of fuel economy data, testing by the administrator.

(a) Fuel economy data must be judged acceptable by the Administrator in order for the test results to be used for the purposes of Subpart C or F of this part. The Administrator will evaluate the acceptability of the fuel economy data from either a fuel economy data vehicle or a certification vehicle on the basis of the data submitted under § 600.006 or test data generated by the Administrator, as applicable, in accordance with good engineering practice.

(b) If, in the Administrator's judgment, the city and highway fuel economy results (or the harmonic averages, as applicable, if more than one test were conducted) for a fuel economy data vehicle, or for a certification vehicle, are reasonable and representative, the Administrator will accept the fuel economy data (or harmonic averages, as applicable, of the city and highway fuel economy data if more than one test was conducted) for use in Subpart C or F. In making this determination, the Administrator will, when possible, compare the results of a test vehicle to those of other similar test vehicles.

(c) If, in the Administrator's judgment, the city and highway fuel economy results (or the harmonic averages if more than one test were conducted) for a fuel economy data vehicle or for a certification vehicle are not reasonable or representative, the Administrator will notify the manufacturer in writing of his finding and require the manufacturer to submit the test vehicle(s) in question, at a place he may designate, for the purpose of fuel economy testing.

(d) The Administrator may require that any fuel economy data vehicle or

certification vehicle be submitted, at a place he may designate, for the purpose of confirmation of fuel economy testing.

(e) For any fuel economy data vehicle that the Administrator has required to be submitted, at a place he may designate for the purpose of fuel economy testing, and for any certification vehicle, the Administrator will follow this procedure:

(1) The manufacturer's data (or harmonically averaged data if more than one test was conducted) will be compared with the results of the Administrator's test.

(2) If, in the Administrator's judgment, the comparison in paragraph (e) (1) of this section indicates a disparity in the data, the Administrator will repeat the city test or the highway test or both as applicable.

(i) The manufacturer's average test results and the results of the Administrator's first test will be compared with the results of the Administrator's second test as in paragraph (e) (1) of this section.

(ii) If, in the Administrator's judgment, both comparisons in (2) (i) indicate a disparity in the data, the Administrator will repeat the city fuel economy test or highway fuel economy test or both as applicable until

(A) In the Administrator's judgment no disparity in the data is indicated by comparison of two tests by the Administrator or by comparison of the manufacturer's average test results and a test by the Administrator, or

(B) Four city tests or four highway tests or both, as applicable, are conducted by the Administrator in which a disparity in the data is indicated when compared as in paragraph (e) (2) of this section.

(3) If there is, in the Administrator's judgment, no disparity indicated by comparison of manufacturer's average test results with a test by the Administrator, the test values generated by the Administrator will be used to represent the vehicle.

(4) If there is, in the Administrator's judgment, no disparity indicated by comparison of two tests by the Administrator, the harmonic averages of the city and highway fuel economy results from those tests will be used to represent the vehicle.

(5) If the situation in paragraph (e) (2) (ii) (B) of this section occurs, the Administrator will notify the manufacturer, in writing, that the Administrator rejects that fuel economy data vehicle.

(f) The fuel economy data determined by the Administrator under paragraph (e) (3) or (4) of this section, together with all other fuel economy data submitted for that vehicle under § 600.006 (c) or (e) will be evaluated for reasonableness and representativeness per paragraph (b) of this section. The fuel economy data which are determined to best meet the criteria of paragraph (b) of this section will be accepted for use in Subpart C or F.

(g) If, based on a review of the fuel economy data generated by testing under paragraph (e) of this section, the Ad-

ministrator determines that an unacceptable level of correlation exists between fuel economy data generated by a manufacturer and fuel economy data generated by the Administrator, he may reject all fuel economy data submitted by the manufacturer until the cause of the discrepancy is determined and the validity of the data is established by the manufacturer.

§ 600.009-77 Hearings on acceptance of test data.

(a) If the Administrator rejects the use of a manufacturer's fuel economy data vehicle, in accordance with § 600.008 (e) or (g), or the use of fuel economy data, in accordance with § 600.008 (c), or (f), or with the determination of a vehicle configuration, in accordance with § 600.206(a), or with the identification of a car line, in accordance with § 600.207(d), or with the fuel economy label values approved by the Administrator under § 600.213(a) the manufacturer may, within 30 days following receipt of such notification, request a hearing on the Administrator's decision. The request may be in writing, signed by an authorized representative of the manufacturer and include a statement specifying the manufacturer's objections to the Administrator's determinations, and data in support of such objection. If, after the review of the request and supporting data, the Administrator finds that the request raises a substantial factual issue, the manufacturer shall have a hearing in accordance with the provisions of this section with respect to such issue.

(b) (1) After granting a request for a hearing under paragraph (a) of this section the Administrator will designate a Presiding Officer for the hearing.

(2) The General Counsel will represent the Environmental Protection Agency in any hearing under this section.

(3) If a time and place for the hearing has not been fixed by the Administrator under paragraph (a) of this section the hearing will be held as soon as practicable at a time and place fixed by the Administrator or by the Presiding Officer.

(c) (1) Upon his appointment pursuant to paragraph (a) of this section, the Presiding Officer shall establish a hearing file. The file consists of the notice issued by the Administrator under paragraph (a) of this section together with any accompanying material, the request for a hearing and the supporting data submitted therewith and correspondence and other data material to the hearing.

(2) The hearing file will be available for inspection by the applicant at the office of the Presiding Officer.

(d) A manufacturer may appear in person, or may be represented by counsel or by any other duly authorized representative.

(e) (1) The Presiding Officer upon the request of any party, or in his discretion, may arrange for a prehearing conference at a time and place specified by the Presiding Officer to consider the following:

(i) Simplification and clarification of the issues;

(ii) Stipulations, admissions of fact, and the introduction of documents;

(iii) Limitation of the number of expert witnesses;

(iv) Possibility of agreement disposing of all or any of the issues in dispute;

(v) Such other matters as may aid in the disposition of the hearing, including such additional tests as may be agreed upon by the parties.

(2) The results of the conference shall be reduced to writing by the Presiding Officer and made part of the record.

(f) (1) Hearings shall be conducted by the Presiding Officer in an informal but orderly and expeditious manner. The parties may offer oral or written evidence, subject to the exclusion by the Presiding Officer of irrelevant, immaterial and repetitious evidence.

(2) Witnesses will not be required to testify under oath. However, the Presiding Officer shall call to the attention of witnesses that their statements may be subject to the provisions of 19 U.S.C. 1001 which imposes penalties for knowingly making false statements or representations, or using false documents in any matter within the jurisdiction of any department or agency of the United States.

(3) Any witnesses may be examined or cross-examined by the Presiding Officer, the parties, or their representatives.

(4) Hearings shall be reported verbatim. Copies of transcripts of proceedings may be purchased by the applicant from the reporter.

(5) All written statements, charts, tabulations, and similar data offered in evidence at the hearing shall, upon a showing satisfactory to the Presiding Officer of their authority, relevancy, and materiality, be received in evidence and shall constitute a part of the record.

(6) Oral argument may be permitted in the discretion of the Presiding Officer and will be reported as part of the record unless otherwise ordered.

(g) (1) The Presiding Officer will make an initial decision which shall include written findings and conclusions and the reasons or basis therefor on all material issues of fact, law or discretion presented on the record. The findings, conclusions, and written decision shall be provided to the parties and made a part of the record. The initial decision shall become the decision of the Administrator without further proceedings unless there is an appeal to the Administrator or motion for review by the Administrator within 20 days of the date the initial decision was filed.

(2) On appeal from or review of the initial decision the Administrator will have all the powers which he would have in making the initial decision including the discretion to require or allow briefs, oral argument, the taking of additional evidence or the remanding to the Presiding Officer for additional proceedings. The decision by the Administration will include written findings and conclusions and the reasons or basis therefor on all the material issues of fact, law or discretion presented on the appeal or considered in the review.

(h) A manufacturer's use of any fuel economy data which the manufacturer challenges pursuant to this section shall not constitute final acceptance by the manufacturer nor prejudice the manufacturer in the exercise of any appeal pursuant to this section challenging such fuel economy data.

Subpart B—Fuel Economy Regulations for 1978 and Later Model Year Automobiles—Test Procedures

§ 600.101-73 General applicability.

The provisions of this subpart are applicable to 1978 and later model year automobiles.

§ 600.102-73 Definitions.

The definitions in § 600.002 apply to this subpart.

§ 600.103-73 Abbreviations.

The abbreviations in § 600.003 apply to this subpart.

§ 600.104-73 Section numbering, construction.

The section numbering system set forth in § 600.004 applies to this subpart.

§ 600.105-73 Record keeping.

The record keeping requirements set forth in § 600.005 apply to this subpart.

§ 600.106-73 Equipment requirements.

The requirements for test equipment to be used for all fuel economy testing are given in §§ 86.106, 86.107, 86.108, 86.109, and 86.111 of this chapter, as applicable.

§ 600.107-73 Fuel specifications.

(a) The test fuel specifications for gasoline-fueled automobiles are given in paragraph (a)(1) of § 86.113 of this chapter.

(b) The test fuel specifications for diesel automobiles are given in paragraphs (b)(1) and (2) of § 86.113 of this chapter.

§ 600.108-73 Analytical gases.

The analytical gases for all fuel economy testing must meet the criteria given in § 86.114 of this chapter.

§ 600.109-73 EPA driving cycles.

(a) The driving cycle to be utilized for generation of the city fuel economy data is prescribed in § 86.115 of this chapter.

(b) The driving cycle to be utilized for generation of the highway fuel economy data is specified in this paragraph.

(1) The Highway Fuel Economy Driving Schedule is set forth in Appendix I to this Part. The driving schedule is defined by a smooth trace drawn through the specified speed versus time relationships.

(2) The speed tolerance at any given time on the dynamometer driving schedule specified in Appendix I, or as printed on a driver's aid chart approved by the Administrator, when conducted to meet the requirements of paragraph (b) of § 600.111 is defined by upper and lower limits. The upper limit is 2 mph higher

than the highest point on trace within 1 second of the given time. The lower limit is 2 mph lower than the lowest point on the trace within 1 second of the given time. Speed variations greater than the tolerances (such as may occur during gear changes) are acceptable provided they occur for less than 2 seconds on any occasion. Speeds lower than those prescribed are acceptable provided the vehicle is operated at maximum available power during such occurrences.

(3) A graphic representation of the range of acceptable speed tolerances is found in paragraph (c) of § 86.115 of this chapter.

§ 600.110-73 Equipment calibration.

The equipment used for fuel economy testing must be calibrated according to the provisions of § 86.116 of this chapter.

§ 600.111-73 Test procedures.

(a) The test procedures to be followed for generation of the city fuel economy data are those prescribed in §§ 86.127 through 86.138 of this chapter, as applicable. (The evaporative loss portion of the test procedure may be omitted unless specifically required by the Administrator.)

(b) The test procedures to be followed for generation of the highway fuel economy data are those specified in § 600.111-73 (b) through (h) inclusive.

(1) The Highway Fuel Economy Dynamometer Procedure consists of a preconditioning highway driving sequence and a measured highway driving sequence.

(2) The highway fuel economy test is designated to simulate non-metropolitan driving with an average speed of 48.6 mph and a maximum speed of 60 mph. The cycle is 10.2 miles long with 0.2 stops per mile and consists of warmed-up vehicle operation on a chassis dynamometer through a specified driving cycle. A proportional part of the diluted exhaust emissions is collected continuously for subsequent analysis using a constant volume (variable dilution) sampler. Diesel dilute exhaust is continuously analyzed for hydrocarbons using a heated sample line and analyzer.

(3) Except in cases of component malfunction or failure, all emission control systems installed on or incorporated in a new motor vehicle must be functioning during all procedures in this subpart. The Administrator may authorize maintenance to correct component malfunction or failure.

(c) Transmissions—The provisions of § 86.128 of this chapter apply for vehicle transmission operation during highway fuel economy testing under this subpart.

(d) Road load power and inertia weight determination—§ 86.129 of this chapter applies for determination of road load power and inertia weight for highway fuel economy testing.

(e) Vehicle preconditioning—The Highway Fuel Economy Dynamometer Procedure is designed to be performed

immediately following the Federal Emission Test Procedure, §§ 86.127 through 86.138 of this chapter. When conditions allow, the tests should be scheduled in this sequence. In the event the tests cannot be scheduled within three hours of the Federal Emission Test Procedure (including one hour hot soak evaporation loss test, if applicable) the vehicle should be preconditioned as in paragraph (e) (1) or (2) of this section, as applicable.

(1) If the vehicle has experienced more than three hours of soak (68° F–86° F) since the completion of the Federal Emission Test Procedure, or has experienced periods of storage outdoors, or in environments where soak temperature is not controlled to 68° F–86° F, the vehicle must be preconditioned by operation on a dynamometer through one cycle of the EPA Urban Dynamometer Driving Schedule, § 86.115 of this chapter.

(2) In unusual circumstances where additional preconditioning is desired by the manufacturer, the provisions of paragraph (a) (3) of § 86.132 of this chapter apply.

(f) Highway Fuel Economy Dynamometer Procedure—

(1) The dynamometer procedure consists of two cycles of the Highway Fuel Economy Driving Schedule (§ 600.109 (b)) separated by 15 seconds of idle. The first cycle of the Highway Fuel Economy Driving Schedule is driven to precondition the test vehicle and the second is driven for the fuel economy measurement.

(2) The provisions of paragraphs (b), (c), (e), (f), (g), and (h) of § 86.135 *Dynamometer procedure* of this chapter, apply for highway fuel economy testing.

(3) Only one exhaust sample and one background sample are collected and analyzed for hydrocarbons (except diesel hydrocarbons which are analyzed continuously), carbon monoxide, and carbon dioxide.

(4) The fuel economy measurement cycle of the test includes two seconds of idle indexed at the beginning of the second cycle and two seconds of idle indexed at the end of the second cycle.

(g) Engine starting and restarting—

(1) If the engine is not running at the initiation of the highway fuel economy test (preconditioning cycle), the start-up procedure must be according to the manufacturer's recommended procedures.

(2) False starts and stalls during the preconditioning cycle must be treated as in paragraphs (d) and (e) of § 86.136 of this chapter. If the vehicle stalls during the measurement cycle of the highway fuel economy test, the test is voided, corrective action may be taken according to § 86.077–25 of this chapter, and the vehicle may be rescheduled for test. The person taking the corrective action shall report the action so that the test records for the vehicle contain a record of the action.

(h) Dynamometer Test Run—The following steps must be taken for each test:

(1) Place the drive wheels of the vehicle on the dynamometer. The vehicle may be driven onto the dynamometer.

(2) Open the vehicle engine compartment cover and position the cooling fan(s) required. Manufacturers may request the use of additional cooling fans for additional engine compartment or under-vehicle cooling and for controlling high tire or brake temperatures during dynamometer operation.

(3) Preparation of the CVS must be performed before the measurement highway-driving cycle.

(4) Equipment preparation—The provisions of paragraphs (b) (3) through (5) inclusive of § 86.137 of this chapter apply for highway fuel economy test except that only one exhaust sample collection bag and one dilution air sample collection bag need be connected to the sample collection systems.

(5) Operate the vehicle over one Highway Fuel Economy Driving Schedule cycle according to the dynamometer driving schedule specified in paragraph (b) of § 600.109.

(6) When the vehicle reaches zero speed at the end of the preconditioning cycle, the driver has 13 seconds to prepare for the emission measurement cycle of the test. Reset and enable the roll revolution counter.

(7) Operate the vehicle over one Highway Fuel Economy Driving Schedule cycle according to the dynamometer driving schedule specified in paragraph (b) of § 600.109 while sampling the exhaust gas.

(8) Sampling must begin two seconds before beginning the first acceleration of the fuel economy measurement cycle and must end two seconds after the end of the deceleration to zero. At the end of the deceleration to zero speed, the roll or shaft revolutions must be recorded.

§ 600.112–73 Exhaust sample analysis.

The exhaust sample analysis must be performed according to § 86.140 of this chapter.

§ 600.113–73 Fuel economy calculations.

The calculations of vehicle fuel economy values require the weighted grams/mile values for HC, CO, and CO₂ for the city fuel economy test and the grams/mile values for HC, CO, and CO₂ for the highway fuel economy test. The city and highway fuel economy values must be calculated by the procedures of this section. A sample calculation appears in Appendix II to this Part.

(a) Calculate the weighted grams/mile values for the city fuel economy test for HC, CO, and CO₂ as specified in § 86.144 of this chapter.

(b) (1) Calculate the mass values for the highway fuel economy test for HC, CO, and CO₂ as specified in paragraph (b) of § 86.144 of this chapter.

(2) Calculate the grams/mile values for the highway test for HC, CO, and CO₂ by dividing the mass values obtained in (b) (1) by the actual distance traveled, measured in miles, as specified in paragraph (h) of § 86.135 of this chapter.

(c) Calculate the city fuel economy and highway fuel economy from grams/mile values for HC, CO, and CO₂. The HC

values (obtained per paragraph (a) or (b) as applicable) used in each calculation in this section are rounded to the nearest 0.01 grams/mile. The CO values (obtained per paragraph (a) or (b) as applicable) used in each calculation in this section are rounded to the nearest 0.1 grams/mile. The CO₂ values (obtained per paragraph (a) or (b) of this section as applicable) used in each calculation in this section are rounded to the nearest gram/mile.

(d) For gasoline-fueled automobiles, calculate the fuel economy in miles per gallon of gasoline by dividing 2421 by the sum of three terms:

- (1) 0.866 multiplied by HC (in grams/mile as obtained in paragraph (c)),
- (2) 0.429 multiplied by CO (in grams/mile as obtained in paragraph (c)), and
- (3) 0.273 multiplied by CO₂ (in grams/mile as obtained in paragraph (c)).

Round to quotient to the nearest 0.1 mile per gallon.

(e) For diesel powered automobiles, calculate the fuel economy in miles per gallon of diesel fuel by dividing 2778 by the sum of three terms:

- (1) 0.866 multiplied by HC (in grams/mile as obtained in paragraph (c) of this section),
- (2) 0.429 multiplied by CO (in grams/mile as obtained in paragraph (c)), and
- (3) 0.273 multiplied by CO₂ (in grams/mile as obtained in paragraph (c)).

Round the quotient to the nearest 0.1 mile per gallon.

Subpart C—Fuel Economy Regulations for 1977 and Later Model Year Automobiles—Procedures for Calculating Fuel Economy Values

§ 600.201–77 General applicability.

The provisions of this subpart are applicable to 1977 and later model year automobiles.

§ 600.202–77 Definitions.

The definitions in § 600.002 apply to this subpart.

§ 600.203–77 Abbreviations.

The abbreviations in § 600.003 apply to this subpart.

§ 600.204–77 Section numbering, construction.

The section numbering system set forth in § 600.004 applies to this subpart.

§ 600.205–77 Record keeping.

The record keeping requirements set forth in § 600.005 apply to this subpart.

§ 600.206–77 Calculation and use of fuel economy values for a vehicle configuration.

(a) Fuel economy values determined for each vehicle and as approved in § 600.008 (b) or (f) are used to determine city, highway, and combined fuel economy values for each vehicle configuration (as determined by the Administrator) for which data are available.

(1) If only one city fuel economy and one highway fuel economy value exist

for a vehicle configuration, those values, rounded to the nearest tenth of a mile per gallon, comprise the city fuel economy value and highway fuel economy value for that configuration.

(2) If more than one city fuel economy value and one highway fuel economy value exist for a vehicle configuration, all values for that vehicle configuration are harmonically averaged and rounded to the nearest 0.0001 of a mile per gallon for the city fuel economy values, and harmonically averaged and rounded to the nearest 0.0001 of a mile per gallon for the highway fuel economy values, in order to determine a city and a highway fuel economy value for that configuration.

(3) The combined fuel economy value for a vehicle configuration is calculated by harmonically averaging the city and highway fuel economy values, as determined in § 600.206(a) (1) and (2), weighted 0.55 and 0.45, respectively, and rounding to 0.0001 of a mile per gallon. A sample of this calculation appears in Appendix II to this Part.

§ 600.207-77 Calculation and use of fuel economy values for a model type.

(a) Fuel economy values for a base level are calculated from vehicle configuration fuel economy values as determined in § 600.206(a) for low altitude tests.

(1) If the Administrator determines that automobiles intended for sale in the State of California are likely to exhibit significant differences in fuel economy from those intended for sale in other states, he will calculate fuel economy values for each base level for vehicles intended for sale in California and for each base level for vehicles intended for sale in the rest of the states.

(2) The manufacturer shall supply model year sales projections for each vehicle configuration within each car line to the Administrator.

(i) Sales projections must be supplied separately for each vehicle configuration intended for sale in California and each configuration intended for sale in the rest of the states if required by the Administrator under paragraph (a) (1) of this section.

(ii) The sales projections must be updated as of the date a manufacturer requests that fuel economy calculations for a model type be made by the Administrator.

(iii) The requirements of this section may be satisfied by providing an amended application for certification, as described in § 86.007-21 of this chapter.

(3) Vehicle configuration fuel economy values, as determined in § 600.206(a), are grouped according to base level.

(i) If only one vehicle configuration within a base level has been tested, the fuel economy value from that vehicle configuration constitutes the fuel economy for that base level.

(ii) If more than one vehicle configuration within a base level have been tested, the vehicle configuration fuel economy values are harmonically averaged in proportion

to the respective projected sales fraction (rounded to the nearest 0.0001) of each vehicle configuration and the resultant fuel economy value rounded to the nearest 0.0001 of a mile per gallon.

(iii) If the Administrator has not accepted test data for at least one vehicle configuration within each base level, the manufacturer shall submit (on or before the date the manufacturer requests the Administrator to calculate the respective general label values), data as specified in § 600.006. The fuel economy data submitted shall be for the vehicle configuration with the largest projected sales within the respective base level.

(4) The procedure specified in § 600.207(a) will be repeated for each base level, thus establishing city, highway, and combined fuel economy values for each base level.

(b) For each model type, as determined by the Administrator, a city, highway, and combined fuel economy value will be calculated by using the projected sales and fuel economy values for each base level within the model type.

(1) If the Administrator determines that automobiles intended for sale in the State of California are likely to exhibit significant differences in fuel economy from those intended for sale in other states, he will calculate fuel economy values for each model type separately for vehicles intended for sale in California and for those intended for sale in the rest of the states.

(2) The sales fraction for each base level is calculated by dividing the projected sales of the base level within the model type by the projected sales of the model type and rounding the quotient to the nearest 0.0001.

(3) The city fuel economy values of the model type (calculated to the nearest 0.0001 mpg) are determined by dividing one by a sum of terms, each of which corresponds to a base level and which is a fraction determined by dividing

(i) The sales fraction of the base level, by

(ii) The city fuel economy value for the respective base level.

(4) The procedure specified in paragraph (b) (3) of this section is repeated in an analogous manner to determine the highway and combined fuel economy values for the model type.

Subpart D [Reserved]

Subpart E [Reserved]

Subpart F—Fuel Economy Regulations for 1978 and Later Model Year Automobiles—Procedures for Determining Manufacturer's Average Fuel Economy

§ 600.501-78 General applicability.

The provisions of this subpart are applicable to 1978 and later model year passenger automobiles.

§ 600.502-78 Definitions.

(a) The definitions in § 600.002 and the following definitions apply to this subpart.

(1) "Declared value" of imported components shall be the value at which components are declared by the importer to

the U.S. Customs Service at the date of entry into the customs territory of the United States, or, with respect to imports into Canada, the declared value of such components as if they were declared as imports into the United States at the date of entry into Canada.

(2) "Cost of production" of a car line shall mean the aggregate of the products of:

(i) The average U.S. dealer wholesale price for such car line as computed from each official dealer price list effective during the course of a model year, and

(ii) The number of passenger cars within the car line produced during the part of the model year that the price list was in effect.

§ 600.503-78 Abbreviations.

The abbreviations in § 600.003 apply to this subpart.

§ 600.504-78 Section numbering, construction.

The section numbering procedure set forth in § 600.004 applies to this subpart.

§ 600.505-78 Record keeping.

The record keeping procedure set forth in § 600.005 applies to this subpart.

§ 600.506-78 Preliminary determination of manufacturer's average.

(a) The manufacturer shall submit for approval by the Administrator, no later than 10 days after his public introduction date, a determination of his preliminary average fuel economy value, calculated according to the procedures in § 600.510 except that:

(1) Sales projections will be used for the calculations in place of the production values, and must be updated at the time of the preliminary calculation.

(2) The fuel economy data used in the calculation shall be that approved by the Administrator as of the public introduction date including:

(i) All fuel economy data from original certification vehicles and fuel economy data vehicles as required by § 600.207.

(ii) Fuel economy data from all vehicles tested for running changes approved under § 86.077-23, and

(iii) Fuel economy data required by paragraph (c).

(b) Minimum data requirements will be established under paragraph (c) of this section for each base level with a sales fraction of 0.0100 or greater (known as a significant base level).

(1) The sales to be used in this determination are those in paragraph (a) (1) of this section.

(2) For the purposes of this section, the sales fraction for a base level shall be the quotient of projected sales of the base level divided by the manufacturer's total projected sales of passenger automobiles, where total projected sales are calculated according to § 600.511 except that projected sales are used in place of production values.

(c) For each significant base level identified in paragraph (b) of this section the manufacturer shall submit prior to public introduction, fuel economy

data for those vehicle configurations, taken in order of decreasing sales (according to the projection submitted in paragraph (a) (1) of this section, whose sales total a minimum of 90 percent of the sales of that base level. For all other base levels, the minimum data requirements of § 600.207(a) (3) (iii) must be met.

(d) All fuel economy data submitted under this subpart must:

(1) Be determined by the test procedures specified in Subpart B or an approved analytical method as permitted under § 600.006(e), and

(2) Be accepted by the Administrator under the requirements of Subpart A.

§ 600.507-78 Running change data requirements.

(a) The manufacturer will be required to submit additional running change fuel economy data for any running change approved under § 86.077-23 which creates a new vehicle configuration in a significant base level originally identified for minimum data under § 600.506 (b), or subsequently identified in § 600.508(b), unless exempted by the Administrator.

(1) The manufacturer may petition the Administrator for an exemption from the requirement to submit additional running change fuel economy data.

(2) If the exemption is not granted, the Administrator will notify the manufacturer of the denial and the manufacturer shall submit running change fuel economy data as prescribed in this section.

(3) If the manufacturer is to generate a credit to be deducted from the amount of civil penalty which has been or may be assessed against him under section 507 (1) of the Act, the manufacturer shall submit additional running change fuel economy data required by this section.

(b) The additional fuel economy data required for a running change in paragraph (a) of this section will be determined based on the sales of the vehicle configurations in the affected base level as updated and submitted to the Administrator at the time of running change approval.

(1) Within each base level identified in paragraph (a) of this section, fuel economy data shall be submitted for the new vehicle configuration, created by the running change, with the greatest projected sales.

(2) Fuel economy data required by this section shall be submitted no later than 30 days after the manufacturer receives approval of the running change for those running changes approved after the calculation of the manufacturer's preliminary average, and no later than 90 days after the calculation of the preliminary average for those running changes approved prior to the calculation of the preliminary average.

(c) Any manufacturer required to submit data under this section as a result of an addition of a base level under § 600.508, must submit data on any running change identified by paragraph (a) of this section.

(1) Data identified by paragraph (a) of this section which were approved prior to the date of approval to add the base level which caused the recalculation of the preliminary average fuel economy value according to § 600.508, must meet the requirements of (b) of this section, except that the data may be submitted at any time before the final calculation of the manufacturer's average fuel economy value in § 600.510.

(2) Any running change identified by paragraph (a) of this section approved on or after that date, must be submitted according to paragraph (b) (2) of this section.

§ 600.508-78 Addition of a base level—data requirements.

(a) Any manufacturer who adds a base level to his product line at any time after the preliminary determination of his average fuel economy value in § 600.506, shall submit in accordance with the requirements of § 600.207, fuel economy and sales projection data for such base level.

(b) If a new base level being added has a sales fraction of 0.0100 or greater (as defined in § 600.506(b) (2)) using sales updated as of the date of receipt of approval to add the base level, the manufacturer shall:

(1) Submit to the Administrator the minimum data required for that base level in accordance with § 600.506(c), and then

(2) Recalculate and submit to the Administrator fuel economy values in accordance with procedures in § 600.506 except that all fuel economy data approved by the Administrator to date shall be used.

(c) If the total projected sales, updated as of the date of approval to add the latest base level, of all base levels added since the initial calculation in § 600.506 is equal to a sales fraction of 0.0300 or greater (as defined in § 600.506 (b) (4)), the manufacturer shall recalculate his average as in paragraph (b) (2).

(d) Any manufacturer required under paragraph (b) or (c) to perform a recalculation may be required by the Administrator to supply any additional data required under § 600.507 regardless of any exemption granted under § 600.507(a), based upon the results of that recalculation.

§ 600.509-78 Voluntary submission of additional data.

(a) The manufacturer may, at his option, submit data in addition to the data required by the Administrator.

(1) Additional fuel economy data may be submitted by the manufacturer for any vehicle configuration which is to be tested as required in § 600.506 or § 600.507 or for which fuel economy data were previously submitted under paragraph (a) (2) of this section.

(2) Within a base level, additional fuel economy data may be submitted by the manufacturer for any vehicle configuration which is not required to be tested by

§ 600.506 or § 600.507. Additional data which is submitted within a base level after the calculation of the manufacturer's preliminary average fuel economy must be submitted in rank order such that data is first submitted for all configurations with a higher sales fraction (as defined in § 600.506(b) (2)).

§ 600.510-78 Determination of average fuel economy.

(a) For each model year, the manufacturer shall submit to the Administrator a report, known as the model year report, containing all information necessary for the calculation of the manufacturer's average fuel economy.

(1) The model year report shall be submitted no later than 60 days after the report required in § 86.078-37 for the final production quarter.

(2) The Administrator may waive the requirement that the model year report be submitted within 60 days after the final quarterly production report. Based upon a request by the manufacturer, if the Administrator determines that 60 days is insufficient time for the manufacturer to provide all additional data required as determined in either § 600.506, 600.507, or 600.508, the Administrator shall establish a date by which the model year report must be submitted.

(3) The model year report must be in writing, signed by an authorized representative of the manufacturer and include the following information:

(i) All fuel economy data used in the preliminary calculation and subsequently required by the Administrator either under §§ 600.506, 600.507, or 600.508.

(ii) All fuel economy data for certification vehicles.

(iii) Any additional fuel economy data submitted by the manufacturer under § 600.509.

(iv) A fuel economy value for each model type for the manufacturer's product line calculated according to paragraph (d).

(v) The manufacturer's average fuel economy value calculated according to paragraph (e) of this section.

(vi) A listing of both domestically and non-domestically produced car lines as determined in § 600.511 and the cost information upon which the determination was made.

(vii) Passenger car production data verified by an independent audit as required by § 600.512.

(b) The fuel economy data utilized in the calculation of the manufacturer's average fuel economy under this subpart is the combined fuel economy value calculated according to § 600.206 for each vehicle configuration for which data has been submitted under paragraph (a) (3) (i), (ii), (iii) of this section.

(c) A fuel economy value for each base level is calculated according to § 600.207 with the exception that actual passenger automobile production data, as required by this subpart, is used instead of sales projections.

(d) A fuel economy value for each model type is calculated according to § 600.207 with the exception that:

(1) Annual passenger automobile production data, as required by this subpart, will be used instead of sales projections.

(2) The fuel economy value of diesel-powered model types will be multiplied by the factor 0.96 to convert gallons of diesel fuel to equivalent gallons of gasoline.

(3) The fuel economy value will be rounded to the nearest 0.0001 mpg.

(e) Average fuel economy will be determined separately for domestically produced and non-domestically produced passenger automobiles and is calculated by dividing:

(1) The total number of passenger automobiles produced in a given model year by a manufacturer, by

(2) A sum of terms, each term of which corresponds to a model type and is a fraction determined by dividing

(i) The number of passenger automobiles of a given model type produced by the manufacturer in the model year, by

(ii) The fuel economy calculated for the model type in accordance with paragraph (d) of this section.

(f) Any reference in this subpart to automobiles produced by a manufacturer shall be deemed to include all automobiles manufactured by persons who control, are controlled by, or are under common control with such manufacturer except those vehicles excluded by § 600.511.

§ 600.511-73 Determination of domestic production.

(a) In calculating average fuel economy under § 600.510, the Administrator will separate the total number of passenger automobiles produced by a manufacturer into the following two categories:

(1) Passenger automobiles which are domestically produced by the manufacturer plus passenger automobiles which are within the includable base import volume of the manufacturer.

(2) Passenger automobiles which are not domestically produced by the manufacturer, are imported by the manufacturer, and are not within the includable base import volume of the manufacturer.

(b) The Administrator will calculate the average fuel economy of each separate category, and, for purposes of this subpart, each category will be treated as if produced by a separate manufacturer.

(c) For purposes of this section:

(1) The term "includable base import volume," with respect to any manufacturer, is the number of passenger automobiles which is the lesser of

(i) The manufacturer's base import volume or

(ii) The number of passenger automobiles calculated by multiplying

(A) The quotient obtained by dividing the manufacturer's base import volume by the manufacturer's base production volume, times

(B) The total number of passenger automobiles produced by the manufacturer during such model year.

(2) The term "base import volume" means one-half the sum of:

(i) The total number of passenger automobiles which were not domestically produced by the manufacturer during the 1974 model year and which were imported by the manufacturer during the 1974 model year, plus

(ii) 133 percent of the total number of passenger automobiles which were not domestically produced by the manufacturer during the first 9 months of model year 1975 and which were imported by the manufacturer during that 9-month period.

(3) The term "base production volume" means one-half of the sum of

(i) The total number of passenger automobiles produced by the manufacturer during model year 1974 plus

(ii) 133 percent of the total number of passenger automobiles produced by the manufacturer during the first 9 months of model year 1975.

(d) For purposes of paragraphs (c) (2) and (c) (3) of this section, any passenger automobile imported during model year 1976, but prior to July 1, 1975, will be deemed to have been produced (and imported) during the first 9 months of model year 1975.

(e) An automobile shall be considered domestically produced in any model year if it is included within a domestically produced car line (car line includes station wagons for purposes of this paragraph), unless the assembly of such automobile is completed in Canada and such automobile is not imported into the United States prior to the expiration of 30 days following the end of the model year. For purposes of this paragraph, a car line will be considered domestically produced if the following ratio is less than 0.25:

(1) The sum of the declared value, as defined in § 600.502, of all of the imported components installed or included on automobiles produced within such a car line within a given model year plus the cost of transportation and insuring such components to the United States or Canadian port of entry but exclusive of any customs duty, divided by

(2) The cost of production, as defined in § 600.502, of automobiles within such car line.

(f) If it is determined by the Administrator at some date later than the date of entry that the declared value of such imported components did not represent fair market value at the date of entry, through U.S. Bureau of Customs appraisals, the Administrator may review the determination made pursuant to paragraph (e) of this section as to whether the pertinent car lines which utilize such components were correctly included within the manufacturer's domestically-produced or foreign-produced fleets. If such a determination was in error due to misrepresentation of the valuation of imported components at the date of entry, the Administrator may recalculate the manufacturer's average for the affected model year, according to § 600.510, to reflect the correct valuation of such imported components in each affected car line.

(g) For purposes of calculations under this paragraph with respect to automobiles manufactured during any model year, an average exchange rate for the country of origin of each imported component shall be used that is calculated by taking the mean of the exchange rates in effect at the end of each quarter set by the Federal Reserve Bank of New York for twelve calendar quarters prior to and including the calendar quarter ending just prior to one year before the public introduction date of such model year. Such rate, once calculated, shall be in effect for the duration of the model year. Upon petition of a manufacturer, the Administrator may permit the use of a different exchange rate where appropriate and necessary.

(h) Components shall be considered imported unless they are either:

(1) Wholly the growth, product or manufacture of the United States and/or Canada, or

(2) Substantially transformed in the United States or Canada into a new and different article of commerce.

(i) The fuel economy of each passenger automobile which is imported by a manufacturer and which is not domestically produced by the manufacturer will be deemed to be equal to the average fuel economy value determined by harmonically averaging, according to the number of passenger automobiles imported, the fuel economy of all passenger automobiles which are imported by the manufacturer and which are not domestically produced by the manufacturer.

§ 600.511-80 Determination of domestic production.

(a) In calculating average fuel economy under § 600.510 the Administrator shall separate the total number of passenger automobiles produced by a manufacturer into the following two categories:

(1) Passenger automobiles which are domestically produced by the manufacturer.

(2) Passenger automobiles which are not domestically produced by the manufacturer.

(b) The Administrator shall calculate the average fuel economy of each separate category, and, for purposes of this subpart, each category shall be treated as if produced by a separate manufacturer.

(c) An automobile shall be considered domestically produced in any model year if it is included within a domestically produced car line (car line includes station wagons for purposes of this paragraph), unless the assembly of such automobile is completed in Canada and such automobile is not imported into the United States prior to the expiration of 30 days following the end of the model year. For purposes of this paragraph, a car line will be considered domestically produced if the following ratio is less than 0.25:

(1) The sum of the declared value, as defined in § 600.502, of all of the imported

components to be installed or included on automobiles within such car line plus the cost of transportation and insuring such components to the United States or Canadian port of entry but exclusive of any customs duty, divided by

(2) The cost of production, as defined in § 600.502, of automobiles.

(d) If it is determined by the Administrator at some date later than the date of entry that the declared value of such imported components did not represent fair market value at the date of entry, through U.S. Bureau of Customs appraisal, the Administrator may review the determination made pursuant to paragraph (c) of this section as to whether the pertinent car lines which utilize such components were correctly included with the manufacturer's domestically-produced or foreign-produced fleets. If such a determination was in error due to misrepresentation of the valuation of imported components at the date of entry, the Administrator may recalculate the manufacturer's average fuel economy for the affected model year, according to § 600.510, to reflect the correct valuation of such imported components in each affected car line.

(e) For purposes of calculations under this section with respect to automobiles manufactured during any model year, an average exchange rate for the country of origin of each imported component shall be used that is calculated by taking the mean of the exchange rates in effect at the end of each quarter set by the Federal Reserve Bank of New York for twelve calendar quarters prior to and including the calendar quarter ending just prior to one year before the public introduction of such model year. Such rate, once calculated, shall be in effect for the duration of the model year. Upon petition of a manufacturer, the Administrator may permit the use of a different exchange rate where appropriate and necessary.

(f) Components shall be considered imported unless they are either:

(1) Wholly the growth, product or manufacture of the United States and/or Canada; or

(2) Substantially transformed in the United States or Canada into a new and different article of commerce.

(g) The fuel economy of each passenger automobile which is imported by a manufacturer and which is not domes-

tically produced by the manufacturer will be deemed to be equal to the average fuel economy value determined by harmonically averaging, according to the number of passenger automobiles imported, the fuel economy of all passenger automobiles which are imported by the manufacturer and which are not domestically produced by the manufacturer.

§ 600.512 Independent audit of production data.

(a) Annual passenger automobile production data, as required by § 600.510(a) (3) must be audited by an independent accountant who will report on its accuracy.

(b) The Administrator will not recognize any person as an accountant who is not duly registered in good standing as such under the laws of the place of his residence or principal office.

(1) The Administrator will not recognize any accountant as independent:

(i) who is not in fact independent with respect to any manufacturer or any of its parents, entities, subsidiaries or other affiliates or,

(ii) who, during the period of his professional engagement to examine the production data being reported on or at the date of his report he or his firm or a member thereof had, or was committed to acquire, any direct financial interest in the manufacturer or any of its parents, entities, subsidiaries or other affiliates or,

(iii) who, during the period of his professional engagement to examine the production data being reported on, at the date of his report or during the period covered by the production data, he or his firm or a member thereof was connected as a promoter, underwriter, voting trustee, director, officer or employee of any manufacturer except that a firm will be deemed independent in regard to a particular manufacturer if a former officer or employee of such manufacturer is employed by the firm and such individual has completely disassociated himself from the manufacturer and its affiliates and does not participate in auditing production data of the manufacturer or its affiliates covering any period of his employment by the manufacturer.

(2) For the purposes of this subpart the term "member" means all partners in the firm and all professional employees participating in the audit or located in an office of the firm participating in a significant portion of the audit.

RULES AND REGULATIONS

APPENDIX I.—HIGHWAY FUEL ECONOMY DRIVING SCHEDULE

*** SPEED (MPH) VS TIME (SEC) ***

SEC	MPH	SEC	MPH	SEC	MPH	SEC	MPH	SEC	MPH	SEC	MPH	SEC	MPH	SEC	MPH	SEC	MPH
0	SAMPLE ON	50	38.6	100	48.5	150	44.1	200	43.4	250	48.0	300	33.4	350	59.0		
1	0.0	51	39.3	101	48.8	151	44.3	201	43.2	251	48.0	301	35.0	351	58.9		
2	0.0	52	40.0	102	49.1	152	44.4	202	43.2	252	48.0	302	37.5	352	58.8		
3	2.0	53	40.7	103	49.2	153	44.6	203	43.1	253	48.1	303	39.1	353	58.6		
4	4.0	54	41.4	104	49.4	154	44.7	204	43.0	254	48.2	304	40.2	354	58.4		
5	6.1	55	42.2	105	49.1	155	44.9	205	43.0	255	48.2	305	41.1	355	58.2		
6	11.3	56	42.9	106	49.0	156	45.2	206	43.1	256	48.1	306	41.8	356	58.1		
7	14.5	57	43.5	107	49.0	157	45.7	207	43.4	257	48.6	307	42.4	357	58.0		
8	17.3	58	44.0	108	49.1	158	45.9	208	43.9	258	48.9	308	42.8	358	57.9		
9	19.6	59	44.3	109	49.2	159	46.3	209	44.0	259	49.1	309	43.3	359	57.8		
10	21.8	60	44.5	110	49.3	160	46.8	210	43.5	260	49.1	310	43.8	360	57.4		
11	24.0	61	44.9	111	49.4	161	46.9	211	42.6	261	49.1	311	44.3	361	57.2		
12	25.8	62	44.9	112	49.5	162	47.0	212	41.5	262	49.1	312	44.7	362	57.1		
13	27.1	63	45.0	113	49.5	163	47.1	213	40.7	263	49.1	313	45.0	363	57.0		
14	28.0	64	45.1	114	49.5	164	47.6	214	40.0	264	49.0	314	45.2	364	57.0		
15	29.0	65	45.4	115	49.4	165	47.9	215	40.0	265	48.9	315	45.4	365	56.9		
16	30.0	66	45.7	116	49.1	166	48.0	216	40.3	266	48.2	316	45.5	366	56.9		
17	30.7	67	46.0	117	48.9	167	48.0	217	41.0	267	47.7	317	45.8	367	56.9		
18	31.5	68	46.3	118	48.6	168	47.9	218	42.0	268	47.5	318	46.0	368	57.0		
19	32.2	69	46.5	119	48.4	169	47.8	219	42.7	269	47.2	319	46.1	369	57.0		
20	32.9	70	46.8	120	48.1	170	47.3	220	43.1	270	46.7	320	46.5	370	57.0		
21	33.5	71	46.9	121	47.7	171	46.7	221	43.2	271	46.2	321	46.8	371	57.0		
22	34.1	72	47.0	122	47.4	172	46.2	222	43.4	272	46.0	322	47.1	372	57.0		
23	34.6	73	47.1	123	47.3	173	45.9	223	43.9	273	45.6	323	47.7	373	57.0		
24	34.9	74	47.2	124	47.5	174	45.7	224	44.3	274	45.6	324	48.1	374	57.0		
25	35.1	75	47.3	125	47.8	175	45.5	225	44.7	275	45.4	325	49.0	375	57.0		
26	35.7	76	47.2	126	47.9	176	45.4	226	45.1	276	45.2	326	49.7	376	57.0		
27	35.9	77	47.1	127	48.0	177	45.3	227	45.0	277	45.0	327	50.3	377	56.9		
28	36.8	78	47.0	128	47.9	178	45.2	228	45.0	278	44.7	328	51.0	378	56.8		
29	37.3	79	46.9	129	47.9	179	45.0	229	45.5	279	44.5	329	51.7	379	56.5		
30	37.9	80	46.9	130	47.9	180	45.1	230	46.9	280	44.2	330	52.4	380	56.2		
31	38.5	81	46.9	131	48.0	181	45.2	231	47.0	281	43.5	331	53.1	381	56.0		
32	39.0	82	47.0	132	48.0	182	41.5	232	47.4	282	42.8	332	53.8	382	56.0		
33	39.8	83	47.1	133	48.1	183	41.5	233	47.5	283	42.8	333	54.5	383	56.0		
34	40.1	84	47.1	134	47.9	184	42.1	234	47.3	284	40.1	334	55.2	384	56.1		
35	40.7	85	47.2	135	47.3	185	42.9	235	47.2	285	38.6	335	55.8	385	56.4		
36	41.1	86	47.1	136	46.8	186	43.8	236	47.2	286	37.9	336	56.4	386	56.7		
37	41.2	87	47.0	137	46.3	187	43.9	237	47.5	287	35.8	337	56.9	387	56.9		
38	41.5	88	46.9	138	46.2	188	43.8	238	47.6	288	34.1	338	57.8	388	57.0		
39	41.7	89	46.5	139	45.5	189	45.3	239	47.9	289	34.0	339	57.1	389	57.3		
40	42.0	90	46.3	140	45.2	190	45.0	240	47.0	290	33.3	340	57.3	390	57.4		
41	42.8	91	46.2	141	45.0	191	45.1	241	46.9	291	32.5	341	57.6	391	57.4		
42	43.0	92	46.3	142	44.9	192	45.5	242	46.8	292	31.7	342	57.8	392	57.2		
43	43.7	93	46.5	143	45.1	193	45.9	243	46.8	293	30.6	343	58.0	393	57.0		
44	43.8	94	46.9	144	45.5	194	46.3	244	47.0	294	29.6	344	58.1	394	56.9		
45	43.8	95	47.1	145	46.1	195	46.6	245	47.2	295	28.4	345	58.4	395	56.6		
46	43.8	96	47.6	146	41.0	196	46.9	246	47.5	296	28.4	346	58.7	396	56.3		
47	43.7	97	47.7	147	42.0	197	46.8	247	47.9	297	28.6	347	58.8	397	56.1		
48	43.7	98	48.0	148	43.1	198	46.9	248	48.0	298	28.5	348	58.9	398	56.4		
49	43.6	99	48.2	149	43.7	199	43.9	249	48.0	299	21.4	349	59.0	399	56.7		
50	51.1	459	58.2	500	54.7	550	55.8	600	48.3	650	50.2	700	54.2	750	76.8		
601	57.5	451	58.1	501	54.6	551	55.0	601	48.0	651	50.7	701	54.5	751	74.5		
602	57.8	452	58.0	502	54.4	552	55.4	602	47.9	652	51.1	702	54.8	752	73.5		
603	58.0	453	58.0	503	54.3	553	55.2	603	47.8	653	51.7	703	55.0	753	73.4		
604	58.0	454	58.0	504	54.3	554	55.1	604	47.7	654	52.2	704	55.5	754	73.4		
605	58.0	455	58.0	505	54.2	555	55.0	605	47.6	655	52.8	705	55.9	755	73.1		
606	58.0	456	58.0	506	54.1	556	54.9	606	48.3	656	52.1	706	56.1	756	72.4		
607	58.3	457	58.0	507	54.1	557	54.6	607	49.0	657	51.5	707	56.1	757	71.7		
608	58.0	458	57.9	508	54.1	558	54.4	608	49.1	658	51.1	708	56.4	758	71.8		
609	57.9	459	57.9	509	54.0	559	54.2	609	49.0	659	51.0	709	56.5	759	71.4		
610	57.8	460	58.0	510	54.0	560	54.1	610	48.9	660	51.0	710	56.7	760	71.3		
611	57.7	461	58.1	511	54.0	561	53.8	611	48.8	661	51.1	711	56.9	761	71.0		
612	57.7	462	58.1	512	54.0	562	53.4	612	48.1	662	51.4	712	57.0	762	70.7		
613	57.8	463	58.2	513	54.0	563	53.3	613	48.2	663	51.7	713	57.1	763	70.8		
614	57.9	464	58.3	514	54.0	564	53.1	614	48.1	664	52.0	714	57.2	764	70.8		
615	58.0	465	58.3	515	54.0	565	52.9	615	48.1	665	52.2	715	57.2	765	70.5		
616	58.1	466	58.3	516	54.0	566	52.6	616	48.2	666	52.5	716	57.3	766	70.4		
617	58.4	467	58.2	517	54.1	567	52.4	617	48.9	667	52.3	717	57.1	767	70.1		
618	58.0	468	58.1	518	54.2	568	52.2	618	48.8	668	52.7	718	57.2	768	69.2		
619	59.1	469	58.0	519	54.5	569	52.1	619	49.5	669	52.6	719	57.1	769	69.1		
620	59.4	470	57.8	520	54.8	570	52.0	620	49.7	670	52.3	720	57.3	770	68.8		
621	59.8	471	57.5	521	54.8	571	52.0	621	50.6	671	52.3	721	57.5	771	68.5		
622	59.9	472	57.1	522	54.9	572	52.3	622	51.5	672	52.4	722	57.6	772	68.1		
623	59.9	473	57.0	523	55.1	573	52.0	623	52.0	673	52.5	723	57.7	773	67.7		
624	59.8	474	56.6	524	55.2	574	52.1	624	52.7	674	52.7	724	57.7	774	67.3		
625	59.6	475	56.1	525	55.2	575	52.0	625	53.0	675	52.4	725	57.1	775	66.8		
626	59.4	476	56.0	526	55.3	576	52.0	626	53.0	676	52.4	726	56.8	776	66.5		
627	59.2	477	55.8	527	55.4	577	51.9	627	53.0	677	52.1	727	56.5	777	66.2		
628	59.1	478	55.5	528	55.5	578	51.4	628	53.1	678	51.7	728	56.2	778	65.9		
629	59.0	479	55.2	529	55.6	579	51.4	629	53.9	679	51.1	729	55.5	779	65.5		
630	58.9	480	55.1	530	55.7	580	51.1	630	54.7	680	50.5	730	54.6	780	65.0		
631	58.7	481	55.0	531	55.6	581	50.7	631	55.1	681	50.1	731	54.1	781</			

SEC	KPH	SEC	KPH	SEC	KPH	SEC	KPH	SEC	KPH	SEC	KPH	SEC	KPH	SEC	KPH
400	91.6	450	93.6	500	94.0	550	94.7	600	77.6	650	89.7	700	87.2	750	43.1
401	92.5	451	93.5	501	97.8	551	97.4	601	77.2	651	81.5	701	87.7	751	39.4
402	93.0	452	93.4	502	97.5	552	97.1	602	77.0	652	82.2	702	88.1	752	34.5
403	93.3	453	93.3	503	97.4	553	96.8	603	76.8	653	83.2	703	89.5	753	31.3
404	93.3	454	93.3	504	97.3	554	96.6	604	76.7	654	83.9	704	89.3	754	27.0
405	93.3	455	93.3	505	97.2	555	96.4	605	76.6	655	84.4	705	89.9	755	24.3
406	93.3	456	93.3	506	97.1	556	96.3	606	76.5	656	85.0	706	90.2	756	20.0
407	93.3	457	93.3	507	97.0	557	96.2	607	76.4	657	85.6	707	90.6	757	15.6
408	93.2	458	93.2	508	96.9	558	96.1	608	76.3	658	86.2	708	90.8	758	11.2
409	93.1	459	93.2	509	96.8	559	96.0	609	76.2	659	86.7	709	90.9	759	8.0
410	92.9	460	93.2	510	96.9	560	96.0	610	76.0	660	87.1	710	91.2	760	5.3
411	92.6	461	93.4	511	96.9	561	96.5	611	76.1	661	87.2	711	91.5	761	3.2
412	92.8	462	93.5	512	96.9	562	96.4	612	76.2	662	87.6	712	91.7	762	1.0
413	92.4	463	93.6	513	96.9	563	96.7	613	76.2	663	88.1	713	92.2	763	0.0
414	93.1	464	93.7	514	96.9	564	96.6	614	76.1	664	88.5	714	92.4	764	0.0
415	93.3	465	93.8	515	96.9	565	96.1	615	76.1	665	88.0	715	92.6	765	0.0
416	93.5	466	93.8	516	96.9	566	96.7	616	76.3	666	88.4	716	92.8	766	0.0
417	94.0	467	93.6	517	97.0	567	96.3	617	75.4	667	88.9	717	93.1	767	0.0
418	94.7	468	93.4	518	97.2	568	96.0	618	76.9	668	89.8	718	93.2	768	0.0
419	95.1	469	93.3	519	97.6	569	95.7	619	76.5	669	90.6	719	93.0	769	0.0
420	95.5	470	93.0	520	98.1	570	95.0	620	76.0	670	91.1	720	94.6	770	0.0
421	96.2	471	92.5	521	98.3	571	95.6	621	76.3	671	92.1	721	94.1	771	0.0
422	96.3	472	91.8	522	98.5	572	95.6	622	76.8	672	92.2	722	93.5	772	0.0
423	96.3	473	91.6	523	98.6	573	95.7	623	76.9	673	92.4	723	92.8	773	0.0
424	96.2	474	91.1	524	98.7	574	95.8	624	76.7	674	92.8	724	92.2	774	0.0
425	95.9	475	90.2	525	98.8	575	95.7	625	76.2	675	93.7	725	91.6	775	0.0
426	95.5	476	90.1	526	98.9	576	95.6	626	76.2	676	94.3	726	91.4	776	0.0
427	95.2	477	89.6	527	99.2	577	95.5	627	76.6	677	93.9	727	90.9	777	0.0
428	95.0	478	89.3	528	99.3	578	95.1	628	77.0	678	93.2	728	90.3	778	0.0
429	94.9	479	88.8	529	99.4	579	95.4	629	77.4	679	93.2	729	89.3	779	0.0
430	94.7	480	88.6	530	99.6	580	95.2	630	76.8	680	91.2	730	87.5	780	0.0
431	94.4	481	88.5	531	99.8	581	95.1	631	76.6	681	92.5	731	87.1	781	0.0
432	94.2	482	88.4	532	99.9	582	95.0	632	76.2	682	93.1	732	86.3	782	0.0
433	94.1	483	88.3	533	99.9	583	95.1	633	76.1	683	93.3	733	85.6	783	0.0
434	94.0	484	88.3	534	99.1	584	95.2	634	76.5	684	93.7	734	85.0	784	0.0
435	93.9	485	88.3	535	99.1	585	95.4	635	76.6	685	94.0	735	84.4	785	0.0
436	93.8	486	88.3	536	99.1	586	95.5	636	76.6	686	94.6	736	83.8	786	0.0
437	93.6	487	88.3	537	99.1	587	95.6	637	76.6	687	95.0	737	83.2	787	0.0
438	93.4	488	88.4	538	99.1	588	95.7	638	76.7	688	95.4	738	81.2	788	0.0
439	93.3	489	88.5	539	99.1	589	95.7	639	77.5	689	95.7	739	79.6	789	0.0
440	93.2	490	88.5	540	99.1	590	95.8	640	76.8	690	91.3	740	78.0	790	0.0
441	93.1	491	88.5	541	99.1	591	95.8	641	76.3	691	92.2	741	76.6	791	0.0
442	93.1	492	88.5	542	99.1	592	95.8	642	76.0	692	92.9	742	75.3	792	0.0
443	93.1	493	88.5	543	99.1	593	95.9	643	76.0	693	93.4	743	73.3	793	0.0
444	93.2	494	88.6	544	99.1	594	95.9	644	76.5	694	93.6	744	71.0	794	0.0
445	93.3	495	88.6	545	99.1	595	95.9	645	76.3	695	93.7	745	68.3	795	0.0
446	93.4	496	88.5	546	99.0	596	95.9	646	76.4	696	94.2	746	63.1	796	0.0
447	93.5	497	88.4	547	99.0	597	95.9	647	77.5	697	95.1	747	57.8	797	0.0
448	93.6	498	88.3	548	99.0	598	95.8	648	76.5	698	95.7	748	52.5	798	0.0
449	93.6	499	88.1	549	99.0	599	95.8	649	76.5	699	96.4	749	47.2	799	0.0

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APPENDIX II.—SAMPLE TEST VALUE CALCULATIONS

(a) Assume that a gasoline-fueled vehicle was tested by the Federal Emission Test Procedure and the following results were calculated:
HC=1.03 grams/mile

$$\begin{aligned} \text{MPG}_c &= \frac{2421}{(0.866 \times \text{HC}) + (0.429 \times \text{CO}) + (0.273 \times \text{CO}_2)} \\ &= \frac{2421}{(0.866 \times 1.03) + (0.429 \times 6.74) + (0.273 \times 785)} \\ &= \frac{2421}{218.1} \\ &= 11.1 \text{ MPG} \end{aligned}$$

(b) Assume that the same vehicle was tested by the Federal Highway Fuel Economy Test Procedure and a calculation similar to that shown in (a) resulted in a highway fuel economy or MPG_h of 18.6. According to the procedure in § 600.113, the combined fuel economy (called MPG_{c/h}) for the vehicle may be calculated by substituting the city and highway fuel economy values into the following equation:

CO=6.74 grams/mile
CO₂=785 grams/mile

According to the procedure in § 600.113, the city fuel economy or MPG_c for the vehicle may be calculated by substituting the HC, CO, and CO₂ gram/mile values into the following equation.

$$\begin{aligned} \text{MPG}_{c/h} &= \frac{1}{\frac{0.55}{\text{MPG}_c} + \frac{0.45}{\text{MPG}_h}} \\ &= \frac{1}{\frac{0.55}{11.1} + \frac{0.45}{18.6}} \\ &= \frac{1}{0.0737} \\ \text{MPG}_{c/h} &= 13.6 \text{ MPG} \end{aligned}$$

[FR Doc.76-26343 Filed 9-9-76;8:45 am]