

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 42

RIN 0581-AC52

[Doc. No. AMS-FV-08-0027; FV-05-332]

United States Standards for Condition of Food Containers

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Agricultural Marketing Service (AMS) proposes to amend the regulations governing the United States (U.S.) Standards for Condition of Food Containers. The proposed revisions would remove the Operating Characteristic (OC) curves for on-line sampling and inspection and make other minor non-substantive changes. These revisions are necessary in order to provide standards that reflect current industry practices.

DATES: Comments must be received on or before March 19, 2012.

ADDRESSES: Interested persons are invited to submit written comments or comments on the Internet. Comments may be sent to Lynne Yedinak, Food Technologist, Processed Products Division, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Room 0709, South Building Stop 0247, Washington, DC 20250-0247; FAX: (202) 690-1527; or Internet: <http://www.regulations.gov>. The current U.S. Standards for Condition of Food Containers is available through the address cited below by accessing the Internet at: http://www.access.gpo.gov/nara/cfr/waisidx_00/7cfr42_00.html. All comments should reference the document number, date, and page number of this issue of the **Federal Register**. All comments will be posted without change, including any personal information provided. All comments submitted in response to this notice will

be included in the record and will be made available to the public on the Internet via: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Lynne Yedinak at the above address, Telephone: (202) 720-9939, Fax: (202) 690-1527, or email FQAStaff@ams.usda.gov.

SUPPLEMENTARY INFORMATION:

Executive Order 12866 Regulatory Flexibility Act

This proposed rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612), AMS has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory action to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Food manufacturers are determined to be small businesses if they have 1,000 or less employees per 13 CFR part 121.

There are approximately 22,058 establishments identified in the 2007 Economic Census as belonging to the North American Industry Classification System under the classification of "food manufacturing" and any number of these establishments could request their product containers be inspected under the provisions of the U.S. Standards for Condition of Food Containers. Only 402 of these establishments would qualify as small businesses under the definition provided by the Small Business Administration.

We have examined the economic implications of this proposed rule on small entities. Under the proposed rule, utilization of the U.S. Standards for Condition of Food Containers continues to be voluntary. Small entities would only incur direct costs when purchasers of their packaged food products stipulate in their procurement documents that the food containers should conform to the requirements of the U.S. Standards for Condition of Food Containers. Since the standards were previously amended in May 1983, innovations in packaging technologies have provided an increasingly wide

variety of acceptable new food containers. These new food containers are not represented by the current standards. Accordingly, we believe that the economic impact of this proposed rule will be minimal because the revisions are necessary in order to provide standards that reflect current industry practices. Finally, the changes concerning removal of OC curves and other non-substantive changes will have no adverse impact on small or large entities.

This rule would not impose any additional reporting or recordkeeping requirements on either small or large establishments. In addition, the Department has not identified any relevant Federal rules that duplicate, overlap, or conflict with the Standards.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988

The rule has been reviewed under Executive Order 12988, Civil Justice Reform. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

Background

The U.S. Standards for Condition of Food Containers (Standards) currently provide sampling procedures and acceptance criteria for the inspection of stationary lots of filled food containers, which includes skip lot sampling and inspection procedures. It also provides on-line sampling and inspection procedures for food containers during production.

Stationary lot sampling is the process of randomly selecting sample units from a lot whose production has been completed. This type of lot is usually stored in a warehouse or in some other storage facility and is offered for inspection.

Skip lot sampling is a special procedure for inspecting stationary lots in which only a fraction of the submitted lots are inspected. Skip lot inspection can only be instituted when a certain number of lots of essentially the same quality have been consecutively accepted.

To be acceptable under the examination criteria in the standards, lots may contain only a limited number of defects classified as minor, major, or critical. Acceptance criteria are based on sampling plans for different lot sizes and levels of inspection such as normal, reduced, or tightened. Defect tables classify the severity of defects.

On-line sampling and inspection is a procedure in which subgroups of sample units or individual containers are selected randomly from pre-designated portions of production. The acceptability of these portions of production is determined by inspecting, at the time of sampling, the subgroups which represent these portions. For this type of sampling, only portions of a lot, rather than a whole lot, may be rejected. This helps to identify trouble spots in a production cycle quickly, and enables the producer to make timely corrections. This can reduce the corrective action costs and the amount of product destroyed as a result of packaging problems.

These standards were developed for use by Government agencies when requested to certify filled primary containers or shipping cases, or both, for condition. The standards are permissive, and they may be used in their entirety or in part by private parties as well.

AMS proposes to revise the Standards to include:

(1) Separating Tables I, I–A, II, II–A, III, III–A, and III–B of sampling plans for normal, tightened, and reduced inspection by the type of sampling plan used (single or double), as well as updating the Acceptable Quality Levels (AQLs) for these tables; (2) Updating Table IV—Metal Containers (Rigid and Semi-Rigid), Table VI—Glass Containers (currently Table V), Table VIII—Rigid and Semi-Rigid Containers (Corrugated or Solid Fiberboard, Chipboard, Wood, Tetra Pak, Gable-Tops, Polymeric Trays, *etc.*) (currently Table VI), Table IX—Flexible Containers (Plastic Bags, Cello, Paper, Textile, Laminated Multi-Layer Pouch, Bag, *etc.*) (currently Table VII), and Table XI—Defects of Label, Marking, or Code (currently Table VIII) to incorporate new defects and revise existing defects to reflect new packaging technologies such as aseptic packaging, metal cans with easy open lids, and plastic rings that hold several containers together; (3) Adding new defect tables, Table V—Composite Containers (Semi-Rigid Laminated or Multi-Layer Paperboard Body with Metal, Plastic, or Combination of Metal and Plastic Ends and a Safety Seal Inside the Cap), Table VII—Plastic Containers (Rigid and Semi-Rigid Bottles, Jars, Tubs, Trays, Pails,

etc.), and Table XII—Interior Can Defects; (4) removing the Operating Characteristic (OC) curves; and (5) other minor non-substantive changes to clarify the text.

These revisions to existing tables, addition of new tables, removal of OC curves, and updating language in the U.S Standards for Condition of Food Containers would enable the standards to be applicable to most types of food containers and align the standards to reflect current industry practices.

OC curves found in §§ 42.140, 42.141, 42.142, and 42.143 from Subpart E—Miscellaneous, are proposed to be completely removed. While these curves show the ability of the various sampling plans to distinguish between accepted and rejected lots, it is our experience that the inclusion of these curves is not critical to use of the standards. Furthermore, they are readily available in literature and on the Internet. Also, Standards for sampling plans including OC Curves are currently available in 7 CFR part 43.

While incorporating the suggested change received during the comment period to the Standards, AMS determined, after further analysis that additional changes were essential to properly reflect current industry practice. These changes included: Critical defect number one in Tables IV—Metal Containers, VI—Glass Containers, and IX—Flexible Containers was incompletely written and reflected inconsistencies with other defects listed in each table; the organization of the defects listed in Table IX—Flexible Containers (Plastic, Cellophane, Paper, Textile, Laminated Multi-Layer Pouch, Bag, *etc.*) did not clearly categorize the defects unique to thermostabilized (heat-treated) products in flexible containers; and that many plastic containers currently utilized by food manufacturers did not belong in Table IX—Flexible Containers (Plastic, Cellophane, Paper, Textile, Laminated Multi-Layer Pouch, Bag, *etc.*) since they maintain their shape when empty.

A proposed rule regarding the revision of the U.S. Standards for Condition of Food Containers was published in the **Federal Register** on November 19, 2009 [74 FR 59920]. A comment period of sixty days was issued which closed on January 19, 2010. AMS received and analyzed two comments in regards to the proposed revisions.

Comments

One commenter requested substances such as BPA not be used in containers. No changes were made based on this

comment as it is outside the scope of the rule.

The other commenter supported the proposed rule revision and provided statements regarding § 42.112—Defects of containers. The commenter stated that while Table IV of § 42.112 has defects for “for” composite cans listed as a subset of the metal can defects, composite cans also exhibit defects consistent with defects listed in Table VI (Rigid and Semi-rigid containers). The comment proposed a separate table be added for composite cans extracting the composite can defects from the two current tables. Based on this comment, AMS removed the composite information in § 42.112 Table IV and added an additional table to § 42.112, Table V. Composite information from Table VI was also included in the new table.

AMS is reproposing the Standards with a sixty-day comment period to provide for all interested persons to comment on AMS’ proposed modifications. All written comments received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 42

Food packaging, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 42 is proposed to be amended as follows:

PART 42—[AMENDED]

1. The authority citation for part 42 continues to read as follows:

Authority: Secs. 203, 205, 60 Stat. 1087, as amended, 1090, as amended (7 U.S.C. 1622, 1624).

2. Section 42.102 is amended by:

a. Removing the definitions

“*Operating Characteristic Curve (OC Curve)*” and “*Probability of acceptance (a) For stationary lot sampling and (b) For On-line Sampling*”.

b. Revising the definitions

“Administrator”, “Lot or inspection lot”, “Sample size (n)”, “Stationary lot sampling” to read as follows:

§ 42.102 Definitions, general.

* * * * *

Administrator. The Administrator of the Agricultural Marketing Service (AMS) of the Department or any other officer or employee of the Agency who is delegated, or who may be delegated the authority to act in the Administrator’s stead.

* * * * *

Lot or inspection lot. A collection of filled food containers of the same size, type, and style. The term shall mean

“inspection lot,” *i.e.*, a collection of units of product from which a sample is to be drawn and inspected to determine conformance with the applicable acceptance criteria. An inspection lot may differ from a collection of units designated as a lot for other purposes (*e.g.*, production lot, shipping lot, *etc.*).

* * * * *

Sample size (n). The number of sample units included in the sample.

* * * * *

Stationary lot sampling. The process of randomly selecting sample units from a lot whose production has been completed. This type of lot is usually stored in a warehouse or in some other storage facility and is offered in its entirety for inspection.

* * * * *

§ 42.106 [Amended]

3. In § 42.106, paragraph (a)(1), remove the word “attributed” and add in its place the word “attributed”.

4. Revise § 42.109, to read as follows:

§ 42.109 Sampling plans for normal condition of container inspection, Tables I and I-A.

TABLE I—SINGLE SAMPLING PLANS FOR NORMAL CONDITION OF CONTAINER INSPECTION

Code	Lot size ranges—number of containers in lot	Type of plan	Acceptable quality levels												
			Origin inspection						Other than origin inspection						
			Sample size	0.25		1.5		6.5		0.25		2.5		10.0	
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
CA	6,000 or less	Single	84	0	1	3	4	9	10	0	1	4	5	13	14
CB	6,001–12,000	Single	168	1	2	5	6	16	17	1	2	7	8	23	24
CC	12,001–36,000	Single	315	2	3	8	9	28	29	2	3	13	14	41	42
CD	Over 36,000	Single	500	3	4	12	13	42	43	3	4	18	19	62	63
CE	Single	800	4	5	18	19	64	65	4	5	27	28	95	96

Ac = Acceptance number.
Re = Rejection number.

BILLING CODE 3410-02-P

Table I-A--Double Sampling Plans for Normal Condition of Container Inspection

Code	Lot size ranges -- Number of containers in lot	Type of Plan	Sample Size	Acceptable quality levels											
				Origin Inspection						Other Than Origin Inspection					
				0.25		1.5		6.5		0.25		2.5		10.0	
Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re				
CA	6,000 or less-----	Double-----	1st-----	(*)	0	4	2	7	(*)	0	4	3	9		
			2d-----	60											
			Total-----	96	(*)	3	4	10	11	(*)	4	5	15	16	
CB	6,001-12,000-----	Double-----	1st-----	0	2	6	10	14	0	2	3	7	14		
			2d-----	60											
			Total-----	180	1	2	5	6	17	18	1	2	8	9	25
CC	12,001-36,000-----	Double-----	1st-----	0	3	7	12	18	0	3	5	10	19		
			2d-----	180											
			Total-----	348	2	3	9	10	31	32	2	3	14	15	45
CD	Over 36,000-----	Double-----	1st-----	0	3	9	15	24	0	3	5	11	23		
			2d-----	288											
			Total-----	516	3	4	12	13	43	44	3	4	19	20	64

(*) = Reject on one or more defects

BILLING CODE 3401-02-C

5. Revise § 42.110, to read as follows:

§ 42.110 Sampling plans for tightened condition of container inspection; Tables II and II-A.

TABLE II—SINGLE SAMPLING PLANS FOR TIGHTENED CONDITION OF CONTAINER INSPECTION

Code	Lot size ranges—number of containers in lot	Type of plan	Acceptable quality levels												
			Origin inspection						Other than origin inspection						
			Sample size	0.25		1.5		6.5		0.25		2.5		10.0	
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
CB	6,000 or less	Single	168	0	1	4	5	11	12	0	1	5	6	16	17
CC	6,001–12,000	Single	315	1	2	6	7	19	20	1	2	8	9	28	29
CD	12,001–36,000	Single	500	2	3	9	10	28	29	2	3	12	13	42	43
CE	Over 36,000	Single	800	3	4	13	14	42	43	3	4	18	19	64	65
CF	Single	1,250	4	5	19	20	63	64	4	5	26	27	96	97

TABLE II—A—DOUBLE SAMPLING PLANS FOR TIGHTENED CONDITION OF CONTAINER INSPECTION

Code	Lot size ranges—number of containers in lot	Type of plan	Sample size	Acceptable quality levels											
				Origin inspection						Other than origin inspection					
				0.25		1.5		6.5		0.25		2.5		10.0	
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
CB	6,000 or less	Double	1st—120	(*)	(*)	2	5	6	10	(*)	(*)	2	6	10	14
			2d—60.												
			Total—180	(*)	(*)	4	5	12	13	(*)	(*)	5	6	17	18
CC	6,001–12,000	Double	1st—168	0	2	1	5	7	13	0	2	2	7	12	18
			2d—180.												
			Total—348	1	2	7	8	21	22	1	2	9	10	31	32
CD	12,001–36,000	Double	1st—228	0	3	2	7	8	17	0	3	3	9	15	24
			2d—288.												
			Total—516	2	3	9	10	29	30	2	3	12	13	43	44
CE	Over 36,000	Double	1st—456	0	4	5	10	21	28	0	4	8	13	32	41
			2d—408.												
			Total—864	3	4	14	15	44	45	3	4	19	20	69	70

(*) = Reject on one or more defects.

6. Revise § 42.111, to read as follows: **§ 42.111 Sampling plans for reduced condition of container inspection, Tables III and III—A; and limit number for reduced inspection, Table III—B.**

TABLE III—SINGLE SAMPLING PLANS FOR REDUCED CONDITION OF CONTAINER INSPECTION

Code	Lot size ranges—number of containers in lot	Type of plan	Acceptable quality levels												
			Origin inspection						Other than origin inspection						
			Sample size	0.25		1.5		6.5		0.25		2.5		10.0	
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
CAA	6,000 or less	Single	29	1	2	1	2	4	5	1	2	2	3	5	6
CA	6,001–36,000	Single	84	1	2	3	4	9	10	1	2	4	5	13	14
CB	Over 36,000	Single	168	1	2	5	6	16	17	1	2	7	8	23	24
CC	Single	315	2	3	8	9	28	29	2	3	13	14	41	42

TABLE III—A—DOUBLE SAMPLING PLANS FOR REDUCED CONDITION OF CONTAINER INSPECTION

Code	Lot size ranges—number of containers in lot	Type of plan	Sample size	Acceptable quality levels											
				Origin inspection						Other than origin inspection					
				0.25		1.5		6.5		0.25		2.5		10.0	
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
CAA	6,000 or less	Double	1st—18	0	2	0	2	1	4	0	2	0	3	2	5
			2d—18.												
			Totals—36	1	2	1	2	5	6	1	2	2	3	6	7
CA	6,001–36,000	Double	1st—36,	0	2	0	4	2	7	0	2	0	4	3	9

TABLE III—A—DOUBLE SAMPLING PLANS FOR REDUCED CONDITION OF CONTAINER INSPECTION—Continued

Code	Lot size ranges— number of containers in lot	Type of plan	Sample size	Acceptable quality levels											
				Origin inspection						Other than origin inspection					
				0.25		1.5		6.5		0.25		2.5		10.0	
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
			2d—60.												
			Total.....96	1	2	3	4	10	11	1	2	4	5	15	16
CB	Over 36,000	Double	1st—120 2d—60.	0	2	2	6	10	14	0	2	3	7	14	19
			Total—180	1	2	5	6	17	18	1	2	8	9	25	26

TABLE III—B—LIMIT NUMBERS FOR REDUCED INSPECTION

Number of sample units from last 10 lots inspected within 6 months	Acceptable quality level				
	0.25	1.5	2.5	6.5	10.0
320–499	(*)	1	4	14	24
500–799	(*)	3	7	25	40
800–1,249	0	7	14	42	68
1,250–1,999	0	13	24	69	110
2,000–3,149	2	22	40	115	181
3,150–4,999	4	38	67	186	293
5,000–7,999	7	63	110	302	472
8,000–12,499	14	105	181	491	765
12,500–19,999	24	169	290	777	1207

* Denotes that the number of sample units from the last 10 inspection lots is not sufficient for reduced inspection for this AQL. In this instance more than 10 inspection lots may be used for the calculations if, the inspection lots used are the most recent ones in sequence within the last 6 months, they have all been on normal inspection, and none has been rejected on original inspection.

7. Section § 42.112, is revised to read **§ 42.112 Defects of containers: Tables IV, V, VI, VII, VIII, IX, and X.**
as follows:

TABLE IV—METAL CONTAINERS (RIGID AND SEMI-RIGID)

Defects	Categories		
	Critical	Major	Minor
Type or size of container or component parts not as specified	None permitted.		
Closure incomplete, not located correctly or not sealed, crimped, or fitted properly:			
(a) Heat processed primary container	1		
(b) Non-heat processed primary container		101	
(c) Other than primary container			201
Dirty, stained, or smeared container			202
Key opening metal containers (when required):			
(a) Key missing		102	
(b) Key does not fit tab		103	
(c) Tab of opening band insufficient to provide accessibility to key		104	
(d) Improper scoring (band would not be removed in one continuous strip)		105	
Metal pop-top:			
(a) Missing or broken pull tab		106	
(b) Missing or incomplete score line		107	
Flexible pop-top:			
(a) Poor seal (wrinkle, entrapped matter, etc.)		108	
(b) Short pull tab			203
(c) Missing pull tab		109	
(d) Torn pull tab			204
Open top with plastic overcap (when required):			
(a) Plastic overcap missing		110	
(b) Plastic overcap warped (making opening or reapplication difficult)		111	
Outside tinplate or coating (when required):			
(a) Missing or incomplete			205
(b) Blistered, flaked, sagged, or wrinkled			206
(c) Scratched or scored			207
(d) Fine cracks			208

TABLE IV—METAL CONTAINERS (RIGID AND SEMI-RIGID)—Continued

Defects	Categories		
	Critical	Major	Minor
Rust (rust stain confined to the top or bottom double seam or rust that can be removed with a soft cloth is not scored a defect):			
(a) Rust stain			209
(b) Pitted rust		112	
Wet cans (excluding refrigerated containers)			210
Dent:			
(a) Materially affecting appearance but not usability			211
(b) Materially affecting usability		113	
Buckle:			
(a) Not involving end seam			212
(b) Extending into the end seam		114	
Collapsed container		115	
Paneled side materially affecting appearance but not usability			213
Solder missing when required		116	
Cable cut exposing seam		117	
Improper side seam		118	
Swell, springer, or flipper (not applicable to gas or pressure packed product or frozen products)	2		
Leaker or blown container	3		
Frozen products only:			
(a) Bulging ends $\frac{3}{16}$ -inch to $\frac{1}{4}$ -inch beyond lip			214
(b) Bulging ends more than $\frac{1}{4}$ -inch beyond lip		119	
Metal drums: leaking filling seal (bung) swell ¹	4	120	

¹ Defect classification depends on the severity of the defect.

TABLE V—COMPOSITE CONTAINERS (FIBERBOARD BODY WITH METAL LIDS OR METAL BOTTOMS, PLASTIC OR FOIL TOP WITH CAP)

Defects	Categories		
	Critical	Major	Minor
Type or size of container or component parts not as specified	None permitted.		
Closure incomplete, not located correctly or not sealed, crimped, or fitted properly:	1		
Dirty, stained, or smeared container			201
Easy open closure:			
(a) Pull tab:			
1. Missing or broken pull tab		101	
2. Missing or incomplete score line		102	
(b) Membrane top:			
1. Poor seal (wrinkle, entrapped matter, etc.)		103	
2. Short pull tab		104	
3. Missing pull tab		105	
4. Torn pull tab		106	
(c) Open top with plastic overcap (when required):			
1. Plastic overcap missing		107	
2. Plastic overcap warped (making opening or reapplication difficult)		108	
Outside tinplate or coating on ends (when required):			
(a) Missing or incomplete			202
(b) Blistered, flaked, sagged, or wrinkled			203
(c) Scratched or scored			204
(d) Fine cracks			205
Collapsed container		109	
Paneled side materially affecting appearance but not usability			206
Leaker	2		
Wet or damp:			
(a) Materially affecting appearance but not usability			207
(b) Materially affecting usability		110	
Crushed or torn area:			
1. Materially affecting appearance but not usability			208
2. Materially affecting usability		111	

TABLE VI—GLASS CONTAINERS (BOTTLES, JARS)

Defects	Categories		
	Critical	Major	Minor
Type or size of container or component parts not as specified	None permitted.		
Closure not sealed, crimped, or fitted properly:			
(a) Heat processed	1		
(b) Non-heat processed		101	
Dirty, stained, or smeared container			201
Chip in glass			202
Stone (unmelted material) in glass			203
Pits in surface of glass			204
Sagging surface			205
Bead (bubble within glass):			
(a) 1/8-inch to 3/16-inch in diameter			206
(b) Exceeding 1/8-inch in diameter		102	
Checked		103	
Thin spot in glass		104	
Blister (structural defect)		105	
Bird swing (glass appendage inside container)	2		
Broken or leaking container	3		
Cap (nonheat processed):			
(a) Cross-threaded			207
(b) Loose but not leaking			208
(c) Pitted rust		106	
Cap (heat processed):			
(a) Cross-threaded or loose	4		
(b) Pitted rust		107	
Sealing tape or cello band (when required):			
(a) Improperly placed			209
(b) Not covering juncture of cap and glass		108	
(c) Ends overlap by less than 1/2-inch		109	
(d) Loose or deteriorating		110	
Missing or torn outer safety seal		111	
Inner safety seal—missing, torn, poor seal		112	

TABLE VII—PLASTIC CONTAINERS (RIGID AND SEMI-RIGID, BOTTLES, JARS, TUBS, TRAYS, PAILS, ETC.)

Defects	Categories		
	Critical	Major	Minor
Type or size of container or component parts not as specified	None permitted.		
Closure not sealed, crimped, or fitted properly:			
(a) Heat processed	1		
(b) Non-heat processed		101	
Dirty, stained, or smeared container			201
Chip in plastic			202
Un-melted gels in plastic			203
Pits in surface of plastic			204
Sagging surface			205
Air bubble within plastic:			
(a) 1/8-inch to 1/16-inch in diameter			206
(b) Exceeding 1/8-inch in diameter		102	
Checked		103	
Thin spot in plastic		104	
Blister (structural defect)		105	
Broken or leaking container	2		
Cap (non-heat processed):			
(a) Cross-threaded			207
(b) Loose but not leaking			208
Cap (heat processed), cross-threaded or loose	3		
Security seals:			
(a) Closure ring missing		106	
(b) Missing or torn outer safety seal		107	
(c) Inner safety seal—missing, torn, or poor seal		108	
(d) Sealing tape or cello band (when required):			
1. Improperly placed			209
2. Not covering juncture of cap and plastic		109	
3. Ends overlap by less than 1/2-inch		110	

TABLE VII—PLASTIC CONTAINERS (RIGID AND SEMI-RIGID, BOTTLES, JARS, TUBS, TRAYS, PAILS, ETC.)—Continued

Defects	Categories		
	Critical	Major	Minor
4. Loose or deteriorating Closure not sealed, crimped, or fitted properly.		111	

TABLE VIII—RIGID AND SEMI-RIGID CONTAINERS—CORRUGATED OR SOLID FIBERBOARD, CHIPBOARD, WOOD, ASEPTIC, POLYMERIC TRAYS, ETC.
[Excluding metal, glass, and plastic]

Defects	Categories		
	Critical	Major	Minor
Type or size of container or component parts not as specified	None permitted.		
Component part missing		101	
Closure not sealed, crimped, or fitted properly:			
(a) Primary container	1		
(b) Other than primary container			201
Dirty, stained, or smeared container			202
Wet or damp (excluding ice packs):			
(a) Materially affecting appearance but not usability			203
(b) Materially affecting usability		102	
Moldy area	2		
Crushed or torn area:			
(a) Materially affecting appearance but not usability			204
(b) Materially affecting usability		103	
Separation of lamination (corrugated fiberboard):			
(a) Materially affecting appearance but not usability			205
(b) Materially affecting usability		104	
Product sifting or leaking		105	
Nails or staples (when required):			
(a) Not as required, insufficient number or improperly positioned			206
(b) Nails or staples protruding		106	
Glue or adhesive (when required); not holding properly, not covering area specified, or not covering sufficient area to hold properly:			
(a) Primary container		107	
(b) Other than primary container			207
Flap:			
(a) Projects beyond edge of container more than 1/4-inch			208
(b) Does not meet properly, allowing space of more than 1/4-inch			209
Sealing tape or strapping (when required):			
(a) Missing		108	
(b) Improperly placed or applied			210
Missing component (straw, etc.)			211
Aseptic containers:			
Missing re-sealable cap or tab		109	
Inner or outer safety seal—missing, torn, poor seal	3		
Thermostabilized polymeric trays:			
Tray body:			
(a) Swollen container	4		
(b) Tear, crack, hole, abrasion through more than one layer of multi-layer laminate for the tray	5		
(c) Presence of delamination in multi-layered laminate			212
(d) Presence of any permanent deformation, such that deformed area is discolored or roughened in texture			213
Lid material:			
(a) Closure seal not continuous along tray flange surface	6		
(b) Foldover wrinkle in seal area extends into the closure seal such that the closure seal is reduced to less than 1/8-inch	7		
(c) Any impression or design on the seal surfaces which conceals or impairs visual detection of seal defects		110	
(d) Areas of "wave-like" striations or wrinkles along the seal area that spans the entire width of seal			214
(e) Abrasion of lid material:			
1. Within 1/16-inch of food product edge of seal such that barrier layer is exposed	8		
2. Greater than 1/16-inch from food product edge of seal that barrier layer is exposed			215
(f) Presence of entrapped matter within 1/16-inch of the food product edge of seal or entrapped moisture or vapor with 1/16-inch of the food product edge of seal that results in less than 1/16-inch of defect free seal width at the outside edge	9		
(g) Presence of any seal defect or anomaly (for example, entrapped moisture, gases, etc.) within 1/16-inch of food product edge of seal		111	

TABLE VIII—RIGID AND SEMI-RIGID CONTAINERS—CORRUGATED OR SOLID FIBERBOARD, CHIPBOARD, WOOD, ASEPTIC, POLYMERIC TRAYS, ETC.—Continued

[Excluding metal, glass, and plastic]

Defects	Categories		
	Critical	Major	Minor
(h) Closure seal width less than 1/8-inch			216

TABLE IX—FLEXIBLE CONTAINERS (PLASTIC, CELLOPHANE, PAPER, TEXTILE, LAMINATED MULTI-LAYER POUCH, BAG, ETC.)

Defects	Categories		
	Critical	Major	Minor
Type or size of container or component parts not as specified	None permitted.		
Closure not sealed, crimped, stitched, or fitted properly:			
(a) Heat processed primary container	1		
(b) Non-heat processed primary container		101	
(c) Other than primary container			201
Dirty, stained, or smeared container			202
Unmelted gels in plastic			203
Torn or cut container or abrasion (non-leaker):			
(a) Materially affecting appearance but not usability			204
(b) Materially affecting usability		102	
Moldy area	2		
Individual packages sticking together or to shipping case (tear when separated)		103	
Not fully covering product		104	
Wet or damp (excluding ice packs):			
(a) Materially affecting appearance but not usability			205
(b) Materially affecting usability Over wrap (when required):		105	
(a) Missing		106	
(b) Loose, not sealed, or closed			206
(c) Improperly applied			207
Sealing tape, strapping, or adhesives (when required):			
(a) Missing		107	
(b) Improperly placed, applied, torn, or wrinkled			208
Tape over bottom and top closures (when required):			
(a) Not covering stitching		108	
(b) Torn (exposing stitching)		109	
(c) Wrinkled (exposing stitching)		110	
(d) Not adhering to bag:			
1. Exposing stitching		111	
2. Not exposing stitching			209
(e) Improper placement			210
Product sifting or leaking:			
(a) Non-heat processed		112	
(b) Heat processed	3		
Flexible pop-top:			
(a) Poor seal (wrinkle, entrapped matter, etc.) reducing intact seal to less than 1/16-inch	4		
(b) Short pull tab (materially affecting usability)			212
(c) Missing pull tab		113	
(d) Torn pull tab (materially affecting usability)			213
Missing component (straw, etc.)			214
Two part container (poly lined box or bag in box):			
(a) Outer case torn			215
(b) Poly liner:			
1. Missing	5		
2. Improper closure		114	
Missing "zip lock" (re-sealable containers)			216
Loss of vacuum (in vacuum-packed)		115	
Pre-formed containers:			
(a) Dented or crushed area			217
(b) Deformed container			218
Missing re-sealable cap		116	
Inner or outer safety seal—missing, torn, poor seal	6		
Air bubble in plastic		117	
Thermostabilized products (includes but not limited to tubes, pouches, etc.):			
Foldover wrinkle in seal area (thermostabilized pouches):			
(a) Extends through all plies across seal area or reduces seal less than 1/16-inch	7		
(b) Does not extend through all plies and effective seal to is 1/16-inch or greater			219
Incomplete seal (thermostabilized pouches)	8		
Non-bonding seal (thermostabilized pouches)	9		

TABLE IX—FLEXIBLE CONTAINERS (PLASTIC, CELLOPHANE, PAPER, TEXTILE, LAMINATED MULTI-LAYER POUCH, BAG, ETC.)—Continued

Defects	Categories		
	Critical	Major	Minor
Laminate separation in body of pouch or in seal within 1/16-inch of food product edge:			
(a) If food contact layer is exposed	10		
(b) If food contact surface is exposed after manipulation or laminate separation expands after manipulation		118	
(c) If lamination separation is limited to isolated spots that do not propagate with manipulation or is outer ply separation in seal within 1/16-inch of food product edge of seal			220
Flex cracks (cracks in foil layer only)			221
Swollen container	11		
Blister (in seal) reducing intact seal to less than 1/16-inch	12		
Compressed seal (overheated to bubble or expose inner layer) reducing intact seal to less than 1/16-inch	13		
Stringy seal (excessive plastic threads showing at edge of seal area)			222
Contaminated seal (entrapped matter) reducing intact seal to less than 1/16-inch	14		
Seal creep (product in pouch “creeping” into seal) reducing intact seal to less than 1/16 inch	15		
Misaligned or crooked seal reducing intact seal to less than 1/16-inch	16		
Seal formed greater than 1-inch from edge of pouch (unclosed edge flaps)			223
Waffling (embossing on surface from retort racks; not scorable unless severe)			224
Poor or missing tear notch (when required)			225

TABLE X—UNITIZING (PLASTIC OR OTHER TYPE OF CASING/UNITIZING)

Defects	Categories	
	Major	Minor
Not specified method	101	
Missing tray (when required)	102	
Missing shrink wrap (when required)	103	
Loose or improperly applied wrap		201
Torn or mutilated		202
Off-center wrap (does not overlap both ends)		203

8. Section 42.113 is revised to read as follows:

§ 42.113 Defects of label, marking, or code.

TABLE XI—LABEL, MARKING, OR CODE

Defects	Categories	
	Major	Minor
Not specified method	101	
Missing (when required)	102	
Loose or improperly applied		201
Torn or mutilated		202
Torn or scratched, obliterating any markings on the label	103	
Text illegible or incomplete		203
Incorrect	104	
In wrong location		204

9. Add § 42.114 to read as follows:

§ 42.114 Procedures for Evaluating Interior Container Defects.

(a) Sections 42.101 through 42.136 of this part provide procedures for determining lot conformance with the U.S. Standards for Condition of Food Containers. This determination is based on the examination of the external characteristics of the food containers.

(b) As an option, if a user of the inspection service requests to have the

interior characteristics of containers examined, and apply these results in the determination of lot acceptability, the defects listed in Table XII of this section may be used.

(c) The determination of lot acceptability based on internal container defects shall be independent of the determination of lot acceptability for U.S. Standards for Condition of Food Containers. A user of the inspection service may choose to require inspection for internal can defects as

well as inspection for U.S. Standards for Condition of Food Containers.

(d) If a user of the inspection service requests an examination for internal container defects in addition to an official USDA/USDC inspection for product quality and/or U.S. grade, the containers opened by the official inspection service for inspection of product quality and/or U.S. grade will be used for examination of interior container defects. The minimum sample size for evaluation of interior container

defects will be 13 containers. As a result, additional containers will be required if the inspection for quality or

U.S. grade calls for fewer than 13 containers. Table XIII of this section provides acceptance numbers for

internal container defects for selected sample sizes.

TABLE XII—INTERIOR CONTAINER DEFECTS

Defects	Categories	
	Major	Minor
De-tinning in metal container materially affecting usability	101
De-tinning in metal container not materially affecting usability	201
Black spots in metal container	202
Enamel missing (when required) in metal container	102
Enamel breakdown in metal container material affecting usability	103
Enamel cracked in metal container material not affecting usability	203
Interior of container damaged materially affecting usability	104
Interior of container damaged not materially affecting usability	204
Other anomaly (ies) of the interior of the container (metal, plastic, paper, rigid, etc.) that materially affects usability	105
Other anomaly (ies) of the interior of the container (metal, plastic, paper, rigid, etc.) that materially affects appearance but not usability	205

TABLE XIII—ACCEPTANCE NUMBERS FOR INTERNAL CONTAINER DEFECTS

Sample size (n = number of containers)	Major		Total	
	Interior defects		Interior defects	
	Ac	Re	Ac	Re
n—13	0	1	2	3
n—21	1	2	3	4
n—29	1	2	4	5
n—38	2	3	5	6
n—48	2	3	6	7
n—60	2	3	7	8

Dated: January 10, 2012.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172, 173, 178, and 180

[Docket No. FDA-2010-F-0320]

United States Pharmacopeial Convention; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by the U.S. Pharmacopeial Convention requesting that the food additive regulations that incorporate by reference food-grade specifications from prior editions of the Food Chemicals

Codex (FCC) be amended to incorporate by reference food-grade specifications from the FCC, 7th Edition.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by February 17, 2012.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, (240) 402-1278.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register on August 10, 2010 (75 FR 48353), FDA announced that a food additive petition (FAP 0A4782) had been filed by U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852. The petition proposes that certain food additive regulations, which incorporate by reference food-grade specifications from prior editions of the FCC, be amended to incorporate by reference food-grade specifications from the FCC, 7th Edition.

Under 21 CFR 171.1(c)(H), either a claim of categorical exclusion under § 25.30 (21 CFR 25.30) or 21 CFR 25.32 or an environmental assessment under 21 CFR. 25.40 is required to be submitted in a food additive petition. A claim of categorical exclusion under § 25.30(i) was submitted with the petition, which applies to corrections and technical changes in regulations. The Agency reviewed the claim of categorical exclusion submitted by the petitioner and stated in the original

filing notice its determination that, under § 25.30(i), the proposed action was of a type that does not individually or cumulatively have a significant effect on the human environment, and therefore, neither an environmental assessment nor an environmental impact statement is required.

However, upon further review of the petition, the Agency has decided that the actions being requested in the petition are neither corrections nor technical changes, and, therefore, the categorical exclusion in § 25.30(i) is not applicable for the proposed action. The Agency informed the petitioner of this decision, who subsequently submitted an environmental assessment.

The potential environmental impact of this petition is being reviewed. To encourage public participation consistent with regulation issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see DATES and ADDRESSES) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the Agency finds that an environmental impact statement