Child Resistant Packaging Standards

This chart shows variances among standards for child resistant packaging. The variances listed below are based on the interpretation of Great Lakes Marketing. If no variances exist between 16CFR1700; follow 16CFR1700. It is always wise to check with the authorizing agency if questions arise or the package is a new design. These notes are for child resistant protocol testing only. Several other standards apply for child resistant packages (i.e., durability, markings, leakage, compatibility, etc.).

Name	16 CFR 1700	CSA Z76.1 - 16	40 CFR 157	ASTM F2517 - 17	ISO 8317-15	ISO 14375:2018	EN 862:2006-02
Title	Poison Prevention Packaging Act (PPPA) of 1970 Regulations.	Reclosable child-resistant packages.	Requirements for child-resistant packaging of pesticide products and devices.	Standard Specification for Determination of Child Resistance of Portable Fuel Containers for Consumer Use.	Child-resistant packaging—requirements and testing procedures for reclosable packages.	Child-resistant non-reclosable packaging for pharmaceutical products.	Requirements and testing procedures for non-reclosable packages for non-pharma-ceutical products.
Related Organization	Consumer Product Safety Commission (CPSC) (as given authority by the PPPA).	Canadian Standards Association (CSA)	United Stated Environmental Protection Agency (EPA)	Association for Standards and Testing Materials (ASTM)	International Standards Organization (ISO/IEC)	International Standards Organization (ISO)	European Community for Standardization (CEN)
Regulates	Packaging for any substance deemed hazardous by CPSC (see 1700.14 for list) sold for use in or around the household.	Reclosable child-resistant packages (this does not apply to non-reclosable packages).	Established under the authority of FIFRA section 25(a)(1)(3) which authorizes standards for package, container or wrapping for pesticide or device.	Container includes the receptacle, spout, retrofit spouts, caps and other closure mechanisms.	Reclosable packages designated as child resistant.	Non-reclosable packaging designated as child resistant.	Child-resistant, non-reclosable, non-pharmaceutical packaging.
Necessary Client Prep and Package Definition	1700.1(b)(3) Immediate package is tested. 1700.20 (A)(ii) Any tamper-resistant feature of the package shall be removed prior to testing unless it is part of the child-resistant design. 1700.20(B) For reclosable packages, the caps are applied using the online torque value at least 72 hours prior to testing. 1700.20(a) Reclosable packages shall be opened and properly resecured one time (or more) by tester or other adult prior to child test.	8.1.1 Non immediate packaging is removed. 8.1.4. f) tamper evident materials are removed. 8.1.4 e) All packages shall contain a placebo.	157.21 Immediate container or wrapping, including any attached closures. 15727 Packaging for each unit ***or*** for the outer retail container which houses the units.	3.1. Containers and closures must meet several other safety standards/requirements. 3.1.3.3 Opening and closing of each closure for 250 cycles. 3.1.4 Containers shall be inverted and inspected visually to determine any leakage.	3.1.1 Only new packages should be tested; each child is given a new package to test. 4.3 Packages are opened and closed once before testing. All tamper evident material is removed. 4.3 Placebo is to be used; quantities are specified.	5.2 Packages for the child panel test shall be unprinted. Each sample package shall be checked for integrity before the test is conducted. There shall be at least 10 unit doses for each child and adult.	4.2 Packages for the child panel test shall be unprinted. Each sample packages shall be checked for integrity before the test.
Child Panel Composition/ Standards	1700.20 • ≤20% from any site • 30% 42-44 months; 40% 45-48 months; 30% 49-51 months • 50% male/female ratio within 10% in each of the three age groups • ≤30% tested by any one tester • Maximum of two packages tested per child; must be of different ASTM types	8.1.2 For 200 child panel: • 40 ± 4 children from each two-month age (42-43, 44-45 months, etc.) • ≤60% of any age group from the same sex 9.1.2 For sequential panel (for child panel only that is not part of a resecuring test): A minimum of 30 children using grid shown in Figure 2.	157.32 References testing protocol of 16CFR1700.20.	4.5.1 Central location testing is allowed. 4.2.4 Same as 16CFR1700.20 4.6.8. Child is told: *"Please try to open this for me or to get the liquid out."*	3.3.1.2: For sequential panels, as few as 30 children can be tested; use Figures 2 and 3. 4.4.2 If a child is used on more than one test panel, it is desirable that there should be at least one week between the tests. 4.4.3 Test sites can be any location in child is relaxed; a minimum of 3 sites is needed.	5.3.2.1 If a child is used for more than one test there shall be at least 4 weeks between tests. Parental or guardian consent shall be obtained before the child is used as part of the test group. 5.3.2.2 Test personnel should visit the site beforehand and become known to the children. A.4 Exclude children involved in a reported poisoning accident.	4.3.2.1 If a child is used for more than one test there shall be at least 4 weeks between tests. Parental or guardian consent shall be obtained before the child is used as a part of the test group. 4.3.2.2 Test personnel should visit the site beforehand and become known to the children. 4.3.2.1 Exclude children involved in a reported poisoning accident. A.1 Parental consent is required.
Sequential Testing	1700.20(a)(iii) Use Figure 1; minimum of 50 children.	9.1.2 Use Figures 2 & 3; minimum of 30 children	Using Figure 1; minimum of 50 children.	4.4 Use Figure 1; minimum of 50 children.	3.3.1.2 Use Figures 2 & 3; minimum of 30 children.	5.4.1.1 Use Figures 2 & 3; minimum of 30 children.	4.4.1.2 Using Figures 2 & 3; minimum of 30 children.

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Name	16 CFR 1700	CSA Z76.1 - 16	40 CFR 157	ASTM F2517 - 17	ISO 8317-15	ISO 14375:2018	EN 862:2006-02
Access to Tools	Tools are not discussed in the protocol. CPSC staff has suggested not giving any tools to the children unless they are included in retail unit of sale. Adults are given tools/implements if their use is explicit in the opening directions.	A.5 No tools or other implements should be given to the children unless supplied as part of the CRP.			4.4.4 No tools are accessible unless supplied as part of the design; if tools are included, attention shall not be drawn to the tools until it is used in the demonstration.	5.3.2.2. No tools shall be accessible unless supplied at point of sale. 5.3.2.2. When tools are needed to open the package, but these are not supplied by the manufacturer, there shall be no demonstration. The test is therefore limited to the first 5 min test period.	4.3.2.2 No tools or implements shall be accessible which might be used by the child, other than those supplied by the manufacturer or packer at the point of sale. When tools are needed to open the package, but these are not supplied by the manufacturer, there shall be no demonstration. The test is therefore limited to the first 5 min test period.
Placebo or Substitute Product	The use of placebo is not discussed in the regulation. For unit dose packages, CPSC staff has recommended using a proper substitute that responses like the intended contents. For other packages, appropriate placebo is used to simulate proper use of the package/dispensing product.	8.1.4 e) All packages shall contain a placebo. Packages shall be filled 1/2 to 2/3 full of the placebo.		3.1.2 Containers, components, and closures shall be new with container one-quarter full of water for testing.	4.3 A suitable substitute product (placebo) shall be used for both the adult and child tests. When a substitute product is used, packages up to a volume of 1 L shall be filled to their normal size capacity (i.e., as sold); packages greater than 1 L volume shall be filled with 1 kg of solid or 1 L of liquid.	5.2 The material and design of the test samples shall conform to the technical specification and they shall be representative of an average batch of original packages.	4.2 An appropriate substitute product shall be used.
Performance Standards	1700.20(B)(ii) Any child who opens the special packaging or gains access to its contents. Failure rate for unit dose packaging is based on toxicological data (or access to the 9th dose). Failure is access in whole in part.	8.1.4 (h) A failure is when a child successfully opens the package.		4.1.1.3 Accessing the liquid from any closure; regardless of which one was demonstrated.	5.1.1 The result of the test is a failure if the child succeeds in opening the package (or gaining access to the contents).	4.2.1 The test shall be considered a failure in relation to unit, strip or blister packages if within 10 min the child accesses more than eight unit doses from the packaging provided.	3.2.1 An individual child test shall be considered a failure in relation to a single use package if the child gains access to one or more units from the packaging provided.
Adult Panel Composition	1700.20(a) • ≤24% from any site; • 25% 50-54 years; 25% 55-59 years; 70% 60-70 years. • 70% female in each of the three age groups • ≤35% tested by any one tester Maximum of two packages tested per sitting; different ASTM types	8.2.1 Unlike child testing, no tester and site limitations are noted.		5.1 Central location testing is permitted. 5.5.7 Seniors are to open and close ALL closures in each time period.		5.2 For both the child and adult tests, there shall be at least 10 unit doses available for each participant. 5.3.3.2 No site or time restrictions.	3.2.2 Adult test is optional unless a tool is supplied to open the container at the point of sale. 4.3.3.1 No more than 30 adults for the panel shall be tested from one site; no tester shall test more than 35% of the panel.
Bracketing/Testing a Series of Packages	Bracketing is NOT discussed. The CPSC staff are open to discussing bracketing.	11.2 Defines an acceptable protocol test series for caps/liners, etc. Not all closure and cap sizes need to be tested.	157.36(b)(2) Registrant must always have test data or test data on a different package with supporting data to prove child resistance.		3.1.2 Details the range of caps and containers in a series that should be tested to reflect the entire series.		
Observers	This is not discussed in the regulation.	A.2 Parents should not be involved or present during testing.			4.4.1.3 Parents should not be involved or present during testing.	5.3.2.2. No observers should be present or near testing (no parents should observe).	

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Adult screening	1700.20(a) Adults unable to open the first package in 5 minutes are asked to open two standard packages with non-CR caps. If this is successful, the participant is included in the panel and counted as a failure. 1700.20(a) Adults must read and sign a consent form.			5.2 Two adult screening packages will be the same as those tested for the child panel but will have conventional closures.	4.5.2 Use screening question: Are you professionally concerned with the design, manufacture or use of child-resistant packaging? Answer must be negative.	5.3.3.1 Use screening questions (and answers must be negative): 1. Are you professionally concerned with the design, manufacture or use of child-resistant packaging? 2. Have you taken part in more than one previous child resistant packaging test within the last 6 months?	4.3.3.1 Use screening question: Are you professionally concerned with the design, manufacture or use of child-resistant packaging?
Certification/ Submissions	1700.14(b) The manufacturer or packer of a regulated substance should submit a sample to the CPSC. 1700.20(c) It is recommended that summary data be given to the CPSC. (Note per the CPSIA, companies putting regulated substances into the market must self-publish a GCC.)		157.34(a) Registrant shall certify to the FDA that packaging meets the stands of 16CFR1700.20.				
Life Testing	1700.20(a) Packages should be opened/closed to represent the life of the package.	12.3 Packages are opened and closed by trained individuals to replicate the lifetime of the package.					
Directive to Child to Use Teeth	1700.20(a) If one or both children have not used their teeth to try to open their packages during the first 5 minutes, tester says: *You can use your teeth if you want to*.				4.4.4 The child is to be told to use whatever means he wants; teeth are not discouraged; however, child are NOT told to use their teeth after the demonstration.	5.3.2.2. No attempt is made to keep a child from using teeth; no permission to use teeth is vocalized.	4.3.2.2 . No attempt is made to keep a child from using teeth; no permission to use teeth is vocalized.
Multiple Closures				4.1.1 Containers with multiple closures shall have each closure accessible. 4.4.1.1 Each closure is tested/demonstrated with a panel of children. Closure(s) not being tested shall be accessible at the same time as would be the likely scenario that a child would encounter the closure. 4.1.1.2 If spout is stored inside can; test with spout in and out of can.			

Test panel	Cumulative number of children	Package openings					
		First 5 minutes			Full 10 minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1	50	0–3	4–10	11+	0–5	6–14	15+
2	100	4–10	11–18	19+	6–15	16–24	25+
3	150	11–18	19–25	26+	16–25	26–34	35+
4	200	19–30	.....	31+	26–40	.....	41+

Figure 1. Pass, continue, and fail criteria for 16 CFR 1700

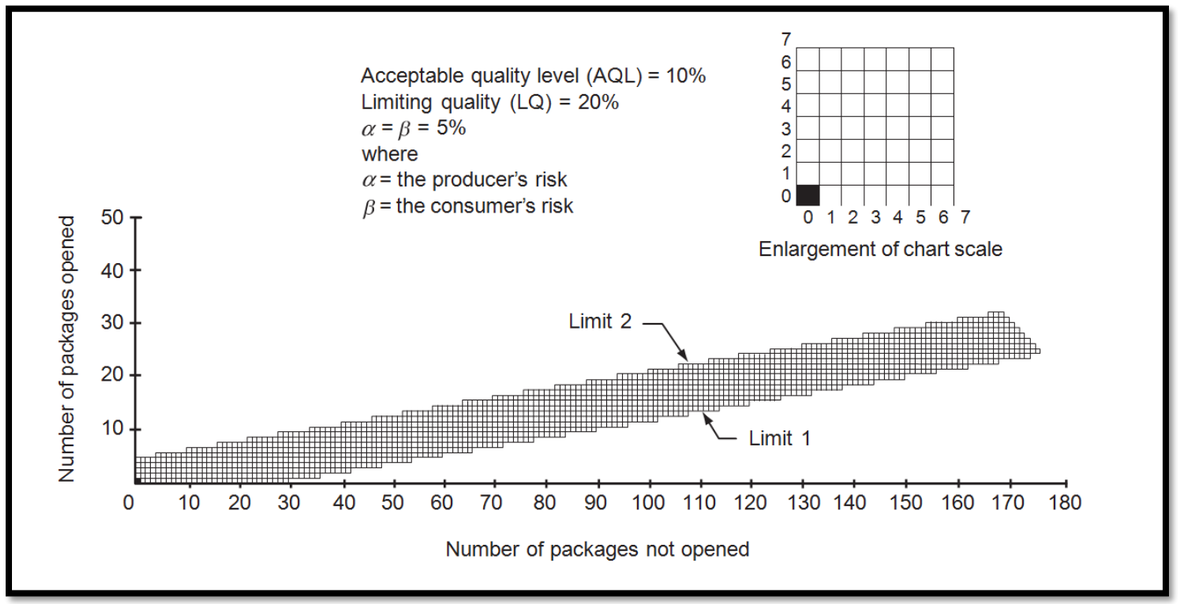

Figure 2. Chart of a sequential child-resistant effectiveness test procedure (without demonstration) for reclosable child-resistant packages

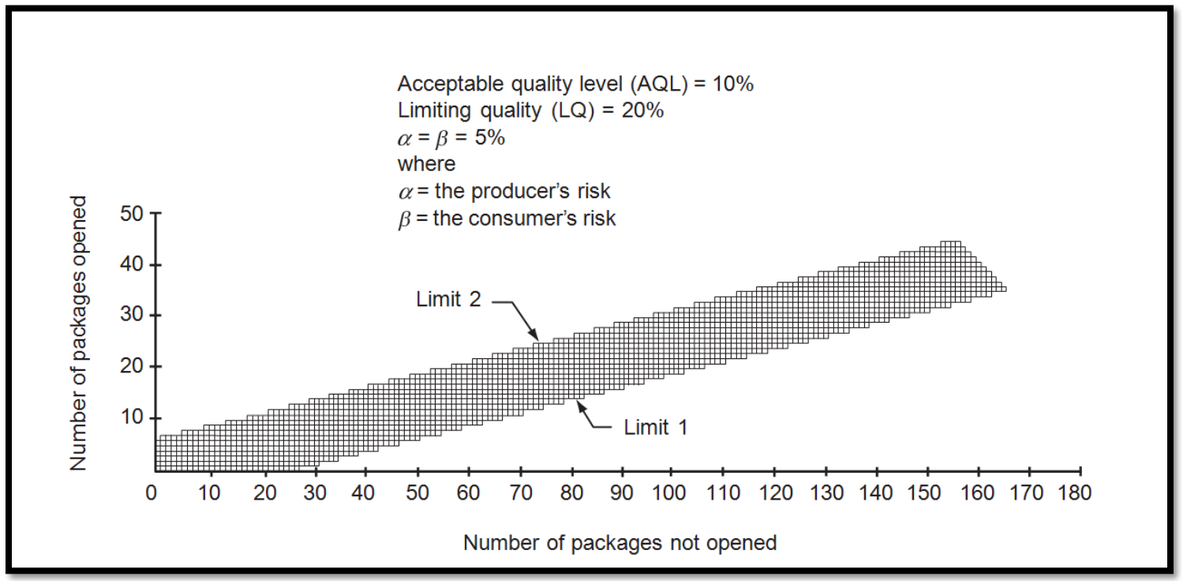

Figure 3. Chart of a sequential child-resistant effectiveness test procedure (after demonstration) for reclosable child-resistant packages