



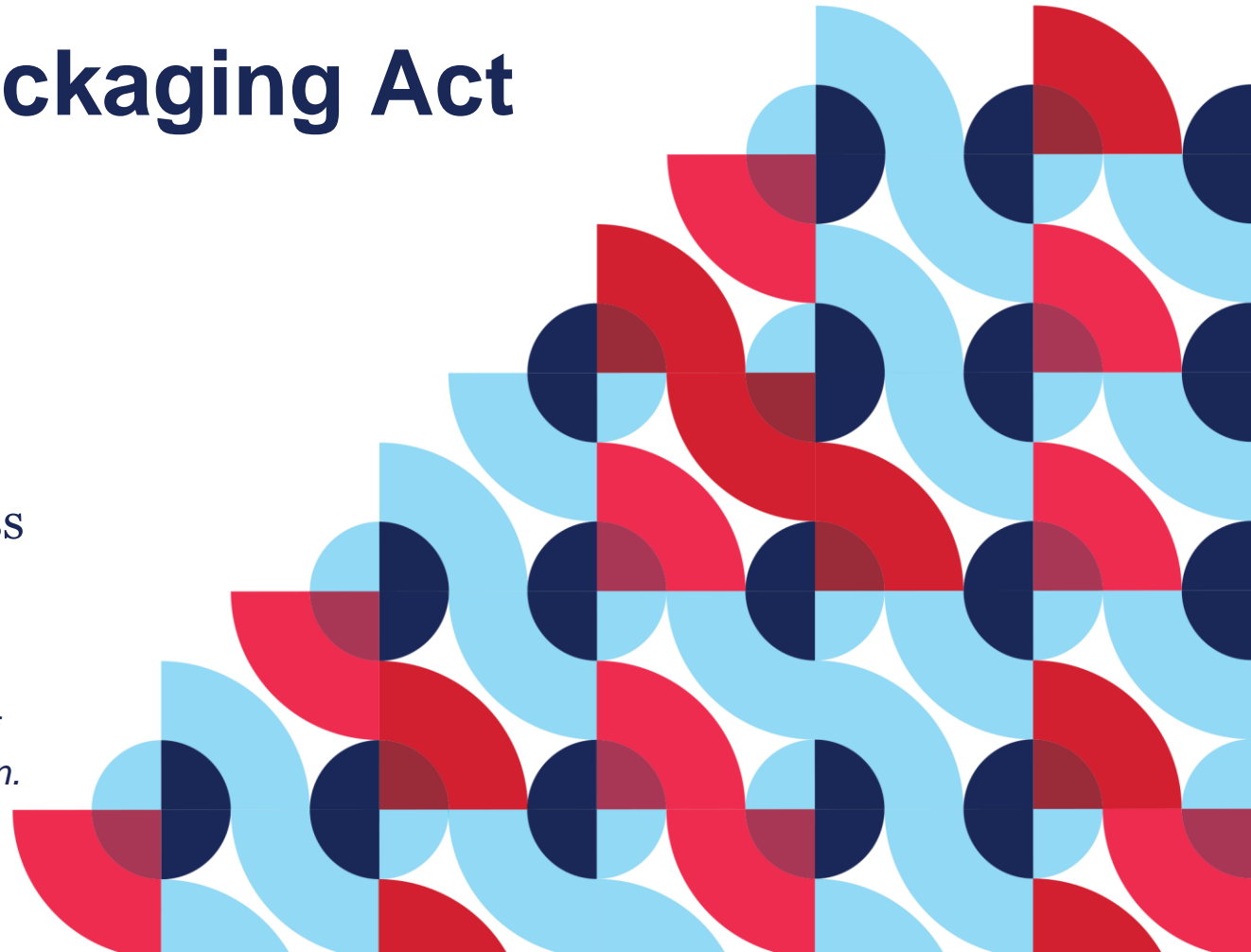
United States  
**Consumer Product Safety Commission**

# Poison Prevention Packaging Act

Webinar  
March 21, 2024

Presented by: Stephen Lee (Small Business  
Ombudsman Team)

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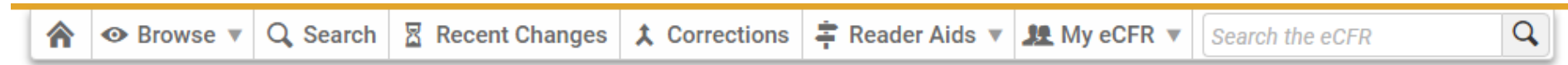
# Poison Prevention Packaging Act

- Special Packaging
- Certification
- Section 15(b) Reporting
- Q & A

[www.cpsc.gov/PPPA](http://www.cpsc.gov/PPPA)

16 CFR part 1700

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# Overview



- Special packaging required for certain household substances
  - List at 16 CFR § 1700.14(a)
  - Requirement can be amount- and form-specific
- CPSC regulates the package, not always the substance
- PPPA requirement applies to the immediate package
- Domestic manufacturer, importer of record, or packer is responsible party
  - Manufacturer means entity putting regulated substance in package



# What is a Household Substance?

- Any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is:
  - A hazardous substance per the Federal Hazardous Substances Act [15 U.S.C. § 1261(f)]
  - A food, drug, or cosmetic per the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321]
  - A fuel stored in a portable container and used in the heating, cooking, or refrigeration system of a house



# What is a Package?

- Immediate container or wrapping in which the substance is contained for consumption, use, or storage by consumers
- Excludes:
  - Bulk packaging
  - Shipping or outer packaging (unless this is the only package)



# What is Special Packaging?

- Packaging that is difficult for children under 5 years of age to open but is not difficult for adults to open
- Commonly referred to as “child-resistant and senior-friendly” or simply “child-resistant”, or CRP (child resistant packaging)
- Erroneously referred to as “child-proof”



# Provisions of Special Packaging

- General requirements
  - Special packaging (e.g., closure) must function for lifetime of package
  - Substance must not affect closure mechanism
- Effective specifications
  - Child test
  - Senior-adult or younger-adult test
- Reuse of special packaging
- Restricted flow
  - Must not dispense more than 2mL when inverted, opened container is taken, squeezed, or activated once



**Q: I only sell products to businesses. Are my products subject to the PPPA?**

This depends on a variety of factors.



# Updated Guidance on Substances Not Intended for Household Use

- Notice issued February 18, 2022
  - Available under “Enforcement Guidance” at [www.cpsc.gov/PPPA](http://www.cpsc.gov/PPPA)
- Marketplace changes, namely increased online sales
  - Manufacturer or re-packager may sell products intended for commercial use, but downstream distributors may resell to consumers
- There is no “institutional use” exception
  - Package cannot simply be labeled “For Institutional Use Only”

**Q: Can you use the same cap on a different bottle than the one that was tested?**

It depends!

Testing must adequately reflect the final product. Glass bottles may be inherently easier to open due to lower coefficient of friction between the bottle and closure threading. Different plastic material (e.g., polypropylene vs low-density polyester) or even different sizes may make it easier to grip and open the bottle.

**Q: If the type of plastic used is changed (e.g., HDPE to PP), do I need to retest?**

Yes.

Different types of plastic can behave differently during the protocol testing; therefore, retesting would be required.



# List of Substances (Drugs)

- Aspirin
- Methyl salicylate
- Controlled drug
- Prescription drug
- Drug containing iron
- Dietary supplement containing iron
- Acetaminophen
- Diphenhydramine
- Ibuprofen
- Loperamide
- Mouthwash
- Lidocaine
- Dibucaine
- Naproxen
- Ketoprofen
- Fluoride
- Minoxidil
- Over-the-counter drug
- Drug/cosmetic containing low-viscosity hydrocarbon
- Imidazoline



# List of Substances (Other)

- Furniture polish
- Sodium/potassium hydroxide
- Turpentine
- Kindling/illuminating preparation
- Methyl alcohol
- Sulfuric acid
- Ethylene glycol
- Solvent for paint or other surface-coating material
- Glue remover containing acetonitrile
- Permanent wave neutralizer containing sodium/potassium bromate
- Methacrylic acid
- Hazardous substance containing low-viscosity hydrocarbon



# Substance Example – Aspirin

- (1) Aspirin. Any aspirin-containing preparation for human use in a dosage form intended for oral administration shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except the following:
- (i) Effervescent tablets containing aspirin, other than those intended for pediatric use, provided the dry tablet contains not more than 15 percent aspirin and has an oral LD-50 in rats of 5 grams or more per kilogram of body weight.
  - (ii) Unflavored aspirin-containing preparations in powder form (other than those intended for pediatric use) that are packaged in unit doses providing not more than 15.4 grains of aspirin per unit dose and that contain no other substance subject to the provisions of this section.



# Substance Example – Sodium/Potassium Hydroxide

- (5) Sodium and/or potassium hydroxide. Household substances in dry forms such as granules, powder, and flakes, containing 10 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, and all other household substances containing 2 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).



## **Q: Are cannabis and similar products subject to the special packaging requirements of the PPPA?**

Sometimes...16 CFR § 1700.14(a)(4) requires controlled drugs in dosage form intended for oral administration subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. § 801 et seq.) to use special packaging. Since marijuana is a schedule I drug, it technically requires special packaging.

Individual states will sometimes incorporate 16 CFR part 1700 as part of the state marijuana laws; firms should contact the agency overseeing state requirements for more information.

**Q: Can equivalent standards (ISO/EN/CSA) be used to certify compliance with the PPPA?**

No.

There are differences between the various standards and PPPA, such as deviations in the testing protocol and even what's considered pass/fail.



# Exemptions and Exceptions

- Bulk drugs intended to be repackaged by pharmacist
- Rx drug, at request of patient or physician
- Rx drug sample
  - 49 FR 8008; March 5, 1984
- After-market drug organizers
- Products not used in or around the household
  - See CPSC's "Updated Guidance on Substances Not Intended for Household Use"



# Noncomplying Package

- One, non-popular size can use conventional packaging
  - Other sizes must use special packaging
- Must be labeled
  - “This package for households without young children” or
  - “Package not child-resistant”
- Liquid drain cleaners containing  $\geq 10\%$  NaOH or KOH not allowed this exemption [16 CFR § 1500.17(a)(4)]
- Does not apply to prescription drugs



# Child Test Protocol

- Up to 4 panels of 50 children, tested in pairs
- Age range 42-51 months old
  - 30% from 42 to 44 months
  - 40% from 45 to 48 months
  - 30% from 49 to 51 months
- Gender restriction: 50% boys and 50% girls
- Tester restriction:  $\leq 30\%$  of the children by single tester
- Site restriction:  $\leq 20\%$  of the children at single site



# Child Test Protocol

- 5-min period, demo, then 2<sup>nd</sup> 5-min period
- Must be effective at least 85% pre-demo and 80% post-demo
- Failure is:
  - Leaking package
  - Opening package or gaining access through any means (e.g., chewing a hole through packaging)
  - For unit-dose, gaining access to number of units (max 9) which produces serious personal injury or illness to a 25 lb. (11.4 kg) child (commonly referred to as f-value)

# Child Test Panel Breakdown



Test Panel	Total Children Tested	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	36-34	35+
4	200	19-30	-	31+	26-40	-	41+



# Child Test Unit Dose Example

Unit dose failures:

	1	2	3	4	5	6	7	8	9
Accessed	3	2	3	1	1	0	1	3	1

	1+	2+	3+	4+	5+	6+	7+	8+	9+
Accessed	15	12	10	7	6	5	5	4	1

Test Panel	Total Children Tested	Package Openings		
		Full 10 minutes		
		Pass	Continue	Fail
1	50	0-5	6-14	15+

[RegulatoryEnforcement@cpsc.gov](mailto:RegulatoryEnforcement@cpsc.gov)





# Senior-Adult Test Protocol

- 100 adults, tested individually
- Age range 50-70 years old
  - 25% from 50 to 54 years
  - 25% from 55 to 59 years
  - 50% from 60 to 70 years
- Gender restriction: 30% male and 70% female
- Tester restriction:  $\leq 35\%$  of the adults by single tester
- Site restriction:  $\leq 24\%$  of the adults at single site



# Senior-Adult Test Protocol

- Consent form
- 5 minutes to open and close, then 1 minute to open and close additional package
  - Screening procedure for ability to open conventional package
- Must be effective at least 90%
  - Must open and close both packages
  - Includes failures during applicable resealing test

# Senior-Adult Test Example

- 92 packages pass senior-adult test (8 failures)
- Pre-calculate 20% (18.4) for acceptable child failures
  - Normal child test allows for 80% effectiveness
- 10 child failures
  - $10 - 18.4 = -8.4 \gg 0$  additional failures
  - $SAUE = 100 - 8 - 0 = 92\%$



# Senior-Adult Test Example

- 92 packages pass senior-adult test (8 failures)
- Pre-calculate 20% (18.4) for acceptable child failures
  - Normal child test allows for 80% effectiveness
- 20 child failures
  - $20 - 18.4 = 1.6$  additional failures
  - $SAUE = 100 - 8 - 1.6 = 90.4\%$



# Senior-Adult Test Example

- 92 packages pass senior-adult test (8 failures)
- Pre-calculate 20% (18.4) for acceptable child failures
  - Normal child test allows for 80% effectiveness
- 21 child failures
  - $21 - 18.4 = 2.6$  additional failures
  - $SAUE = 100 - 8 - 2.6 = 89.4\%$





# Younger-Adult Test Protocol

- 100 adults, tested individually
- Age range 18-45 years old
- Gender restriction: 30% male and 70% female
- Tester restriction: no more than 35% of the adults by single tester
- Site restriction: no more than 35% of the adults at single site



# Younger-Adult Test Protocol

- Applicable for products in aerosol form and products that require metal containers
  - Firm must show a need for such container [16 CFR § 1700.15(b)(2)(ii)(B)]
- Used in lieu of senior-adult test
- 5 minutes to open and close
- Must be effective at least 90%
  - Includes failures during applicable resealing test



# General Certificate of Conformity (GCC)

- Section 14(a) of the Consumer Product Safety Act: Certification required for products subject to consumer product safety rule, standard, ban, or regulation
- Domestic manufacturer or importer must generate and maintain GCC
- Testing for compliance with the PPPA does not need to be conducted by a third-party, CPSC-accepted laboratory



**Q: I was provided a test report/certificate from my bottle supplier. Do I need to create a GCC?**

Yes, if you're the entity introducing the regulated substance to the packaging.

Under 16 CFR part 1109, the manufacturer of the finished product (entity introducing the regulated substance to the package) may rely on a third party's test report or certificate (if certain requirements are met); however, such firms must still generate their own GCC for the finished product.



# GCC Elements

- 1) Identification of the product
- 2) Citation to each safety rule
- 3) Identification of importer or domestic manufacturer
- 4) Contact information for individual maintaining test results
- 5) Date and place of manufacture
- 6) Date and place of testing
- 7) Identification of testing laboratory

# GCC Example



- 1) Identification of the product
- 2) Citation to each safety rule
- 3) Identification of importer or domestic manufacturer
- 4) Contact information for individual maintaining test results
- 5) Date and place of manufacture
- 6) Date and place of testing
- 7) Identification of testing laboratory

~~28-400 white PP continuous thread  
closure with HDPE bottle~~

123 Pain-be-Gon aspirin  
Dosage: 81 mg, 325 mg, 500 mg  
Counts: 100, 300, 500



# GCC Example

- 1) Identification of the product
- 2) Citation to each safety rule
- 3) Identification of importer or domestic manufacturer
- 4) Contact information for individual maintaining test results
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- 6) Date and place of testing
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16 CFR part 1700 – Poison Prevention Packaging

# GCC Example



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- 5) Date and place of manufacture
- 6) Date and place of testing
- 7) Identification of testing laboratory

~~Empty Bottle Suppliers, Co.  
1 Bottle St  
Bethesda, MD 20814~~

123 Pain-be-Gon  
999 Industry Ln, Suite A  
Los Angeles, CA 90001  
(123) 456-7890



# GCC Example

- 1) Identification of the product
- 2) Citation to each safety rule
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- 4) Contact information for individual maintaining test results
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- 6) Date and place of testing
- 7) Identification of testing laboratory

John Smith, Compliance Manager

Empty Bottle Suppliers, Co.

1 Bottle St

Bethesda, MD 20814

j.smith@ebsco.com

(555) 555-5555 x55

# GCC Example



- 1) Identification of the product
- 2) Citation to each safety rule
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Sep 2021 to Present  
Los Angeles, CA, USA

123 Pain-be-Gon	Empty Bottle Suppliers, Co.
999 Industry Ln, Suite A	1 Bottle St
Los Angeles, CA 90001	Bethesda, MD 20814

# GCC Example



- 1) Identification of the product
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Jan 2020

Flushing, NY and surrounding area



# GCC Example



- 1) Identification of the product
- 2) Citation to each safety rule
- 3) Identification of importer or domestic manufacturer
- 4) Contact information for individual maintaining test results
- 5) Date and place of manufacture
- 6) Date and place of testing
- 7) Identification of testing laboratory

Package Testers, Inc.  
111 Package Dr, Suite 100  
Flushing, NY 11354  
(999) 999-9999 x9999



# Other Standards Referencing Special Packaging

- 15 U.S.C. § 1472a – Liquid nicotine packaging
  - Restricted flow is a requirement for such packaging
- 16 CFR part 1460 – Portable gasoline/kerosene/diesel fuel container
- P.L. 117-171 § 3(a) – Button cell or coin battery packaging

**Q: My testing was done 10 years ago. Is it still valid?**

Yes, assuming there were no material changes since the original test.

There may be a larger question of whether there really weren't any material changes...



# When should products be retested?

- Changes in the manufacturing
  - Raw materials (e.g., source of plastic pellets)
  - Actual manufacturing process (e.g., switching out injectors)
  - New package design
- Swapping out package type, size, shape
- Receipt of incident reports or complaints
- Manufacturing defects



# Section 15(b) Reporting

- Under section 15(b) of the CPSA, firms must report:
  - Defective products that pose a substantial risk of injury
  - Product that creates an unreasonable risk of serious injury or death
  - Product that fails to comply with a consumer product safety rule or any other rule, regulation, standard, or ban enforced by the Commission
- Initial reports submitted “immediately” upon receipt of information related to product issues/incidents
  - 16 CFR § 1115.13(c)
- Full reports required
  - 16 CFR § 1115.13(d)



# Section 15(b) Reporting

- Reporting methods:
  - Online at [www.saferproducts.gov](http://www.saferproducts.gov)
  - Email to [Section15@cpsc.gov](mailto:Section15@cpsc.gov), include “Section 15b report” or similar language in the subject line
- Reporting does not mean a case will be opened or that additional corrective actions will be required
- Submissions are treated as confidential as allowed by law

# Contact us!

[www.cpsc.gov/SBOContact](http://www.cpsc.gov/SBOContact)

Toll Free: (888) 531-9070

[SBO@cpsc.gov](mailto:SBO@cpsc.gov)

[www.cpsc.gov/Email](http://www.cpsc.gov/Email)

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