



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

February 27, 1996

PR NOTICE 96-2

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS  
AND REGISTRANTS OF PESTICIDES

**ATTENTION:** Persons Responsible For Registration of Pesticides,  
Manufacturers of Child-Resistant Packaging, and Persons  
Responsible for The Testing of Child-Resistant Packaging

**SUBJECT:** CHANGES TO CHILD-RESISTANT PACKAGING (CRP)  
TESTING REQUIREMENTS

**PURPOSE**

This notice announces revisions to the effectiveness standards applicable to child-resistant packaging (CRP). The EPA's CRP regulations at 40 CFR 157.32 reference the Consumer Product Safety Commission (CPSC) packaging standards and testing procedures for CRP (16 CFR 1700.15(b) and 1700.20). The EPA reference to 16 CFR 1700.15(b) and 1700.20 always refers to the most recent version of these regulations. The CPSC has published a final rule in the Federal Register revising its CRP packaging standards and testing procedures. 60 FR 37710 (July 21, 1995). Consequently, the packaging standards and testing procedures pesticide registrants are required to comply with have changed. This notice explains the CPSC revisions to 16 CFR 1700.15(b) and 1700.20 for pesticide registrants subject to CRP requirements.

This PR Notice becomes effective upon the date of signature by the Agency. **All pesticides** subject to the CRP regulations and **packaged and released for shipment on or after January 21, 1998** (30 months after publication of the CPSC final rule) **must comply with the mandatory provisions of the new effectiveness standards and protocol test procedures.**

## **BACKGROUND**

FIFRA 25(c)(3) requires EPA's CRP standards to be consistent with those established under the Poison Prevention Packaging Act of 1970 (PPPA). The CPSC is authorized by the PPPA to issue requirements that certain household substances, excluding pesticides, be sold in CRP. To avoid duplicative testing of packages for pesticidal and nonpesticidal purposes, EPA CRP regulations reference the CPSC regulations.

In order to comply with the CRP standards, a package must resist entry by most young children and must not be difficult for most adults to open and properly resecure, within a specified time period in testing. CPSC has concluded that more effective CRP is necessary to reduce accidental ingestion of products by young children. It has been observed that some persons, especially older persons, find certain types of CRP difficult to open and resecure properly. Therefore, a number of people either purchase products in packages that are not child-resistant or do not properly resecure the package after opening it initially.

The CPSC has determined that if these difficult-to-use packages were replaced with packages that are easier to use, more people would purchase and properly use CRP, with a reduction in the number of poisonings to young children.

EPA is in agreement with the CPSC's conclusion that if these difficult-to-use packages were replaced with packages that are easier to use, more people would purchase and properly use CRP. EPA believes that adopting CPSC's revised protocol requirements will reduce the need for duplicative testing of packages for pesticidal and nonpesticidal purposes, improve the effectiveness of CRP, and reduce the injuries to children from pesticides as packaged.

## **TEST CHANGES**

The revisions to the adult test were issued to increase the use of child-resistant packaging by making it easier for adults to open. The revisions to the adult test substitute 100 older adults (50-70 years old) for the current adult panel. The senior adult panel involves two test periods, 5 minutes and 1 minute. Products that must be packaged in metal containers or in aerosol form are exempt from the senior adult panel, but remain subject to the current 18-45 year old test panel, the younger adult panel. The revisions to the child test include sequential testing, which will make the test easier to perform. For all the tests, the number of subjects tested by any one tester and at any one site are limited. Also, standardized instructions are required for the child and senior adult tests, which make the test results more consistent without adversely affecting the ability of the test to determine child-resistance.

## **SUMMARY OF CHANGES TO THE PACKAGING STANDARDS AND TESTING PROCEDURES**

**Note: Consult the CPSC Federal Register (FR) Notice attached to this document for the details on how to conduct the test, conditions of packages to be tested, age and gender distribution, test instructions, screening test, number of test sites and testers, sequential testing, numbers of package openings for child-resistance, senior adult use effectiveness, adult-resecuring test, aerosol/metal container exemption, and the applicability of the various tests. A brief summary of the testing procedures is provided below.**

### **SENIOR ADULT TEST**

- o Senior adult test panel consists of 100 seniors **50-70 years old** (50-54 years old 25%, 55-59 years old 25%, 60-70 years old 50%), 70% of whom are female.
- o The test includes a 5 minute test period followed by a 1 minute test period. The senior adult use effectiveness (SAUE) must be  $\geq 90\%$ .
- o Subjects who do **not** open the test package in the first 5 minutes are screened with two non-CR packages (a snap and a continuous-threaded plastic closure) and are given 1 minute to open and properly reclose each of the two non-CRs. Only persons who pass the non-CR screening test (open and properly reclose both non-CRs) are included in the panel.
- o A pass on the Senior Adult Test involves opening the test package in the 5 minute test period and opening and properly resealing the test package in the second 1 minute test period. A pass for unit dose packaging involves opening a single (unit) package during both test periods.
- o Adults are tested individually. A new identical package is used for the second 1 minute test period. The adults shall receive only such printed instructions on opening and properly resealing the CRP as will appear on or accompany it to the consumer.
- o Numbers of testers and test sites are limited such that there is a maximum of 24% senior adults/site and 35% senior adults/tester.

This test does not apply to pesticides that must be packaged in metal containers or in aerosol form that meet specific criteria. Those pesticides will remain subject to the younger adult test requirements.

### YOUNGER ADULT TEST

- o The younger adult test panel consists of 100 adults 18-45 years old, 70% of whom are female. Participants are given a 5 minute test period to open and properly resecure the package. The younger adult use effectiveness (YAUE) shall be  $\geq 90\%$ .
- o A pass involves successfully opening the CRP and properly resealing it (if appropriate) in a 5 minute test period. In the case of unit packaging, a pass involves the successful opening of a single package.
- o The younger adults are tested individually. The adults shall receive only such printed instructions on opening and properly resealing the CRP as will appear on or accompany it to the consumer.
- o Numbers of testers and test sites are limited such that there is a maximum of 35% younger adults/site and 35% younger adults/tester.

### CHILD TEST

- o The sequential child test uses 1-4 groups of 50 children 42-51 months old (may total 200 children) with no more than a 10% preponderance of either gender within each age group. Each group of 50 children must contain an age distribution of 42-44 months (30%), 45-48 months (40%), and 49-51 months (30%).
- o The test consists of allowing the children 5 minutes to open the package or gain access to its contents. If either child has not opened his or her package, the tester shall demonstrate how to open the package. If the children have not tried to use their teeth they are told they may do so, and a second 5 minutes is allowed to open the package or gain access to its contents. A sequential chart on when to pass/fail/continue the testing is given in the FR.
- o The child-resistant effectiveness shall be  $\geq 85\%$  without a demonstration and  $\geq 80\%$  with a demonstration. In the case of unit packaging, child-resistant effectiveness shall be  $\geq 80\%$  (when 200 children are tested).
- o A failure is when the child opens the package or gains access to its contents. For a unit dose, a failure is when a sufficient number of packages are opened or gained access to which constitute the amount that may produce serious personal injury or illness (based on a 25 pound/11.4 kg child) or more than 8 individual units, whichever number is lower, during the 10 minute test. The number of units that a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part.

- o The children are tested in groups of 2 in a location familiar to them. No child shall test more than 2 packages and they shall be a different ASTM type.
- o Numbers of testers and test sites **in each sequential group of 50** such that there is a maximum of 30% children/tester and 20% children/site.

## OTHER CHANGES

### ADULT-RESECURING TEST

- o An adult resecuring test for CRP is recommended when an objective determination cannot be made that the package is properly resecured (visual or mechanical observations are not reliable, e.g., continuously threaded closures).
- o The adult resecuring test involves taking the packages from the senior adult test or the younger adult test which appear to be resecured and subjecting them to a child test.
- o The CPSC regulations discuss adult use effectiveness for this test in paragraph 3.a. of section 1700.20(d)(2), which states:

"1. The number of adult opening and resecuring failures, plus the number of packages that were opened by the children during the full 10-minute test that exceeds 20% of the apparently-resecured packages, equals the total number of failures.

2. The total number of packages tested by adults (which is 100) minus the total number of failures equals the percent adult-use effectiveness."

### AEROSOL/METAL CONTAINER EXEMPTION

- o Aerosol products that are self-contained pressurized products and metal containers that consist of a metal package and metal closure are exempt from the senior adult test provided they meet certain criteria (see section 1700.15(b)(2)(ii)(B)(1)). Manufacturers of products or packages should have proof of why a product qualifies for this exemption.
- o These aerosol and metal container products must comply with the younger adult test (16 CFR 1700.20(a)(4)) and have an effectiveness of  $\geq 90\%$ . These products are **still subject to** the revised child test.
- o Certain products may not qualify for the metal container exemption if the product or another product with identical composition has been or is being marketed in packaging or a closure that is not metal. In this case, it is presumed that such a product does not require a metal container.

CONDITION OF PACKAGES TO BE TESTED is described in section 1700.20(a)(1)(ii) of the CPSC regulations, page 37735 of the FR.

### COMPLIANCE DATES AND AGENCY ACTION

- o Effective dates for the new requirements as they pertain to products under CPSC jurisdiction are set out at page 37734 of the FR notice.
- o Rather than using the four different effective dates for implementing the revisions to 16 CFR 1700.15(b) and 1700.20 as indicated in the CPSC FR Notice, EPA will utilize one effective date. The rationale for EPA employing one effective date is to allow for the worse case scenario, i.e., a package needs to be tested for compliance with the senior adult test first, then the package is tested for resealing (if applicable) and child-resistance.
- o All pesticides subject to the CRP regulations and **packaged and released for shipment on or after January 21, 1998** (30 months after publication of the CPSC FR Notice ) **must comply with the mandatory provisions of the new effectiveness standards and protocol test procedures.**

An adequate supply of CRP in compliance with the new effectiveness standards and protocol test procedures is expected to be developed in response to the CPSC regulations. The majority of pesticide products use the same CRP as that used by products under the CPSC jurisdiction. It is expected that CRP in compliance with the new effectiveness standards and protocol test procedures will be technically feasible, practicable, and appropriate (as defined in 40 CFR Part 157).

Existing CRP and their certifications will not be grandfathered into compliance. Anyone who has a pesticide subject to CRP requirements and cannot obtain CRP in compliance with the new effectiveness standards and protocol test procedures by January 21, 1998 may request an exemption under 40 CFR 157.24. The exemption request should be sent to Rosalind L. Gross at the address given below. The registrant should provide information (as described in 40 CFR 157.24) justifying the exemption request along with toxicity information regarding which of the toxicity criteria (including numeric values and MRID numbers) under 40 CFR 157.22 necessitate the product to be in CRP. The Agency will evaluate these exemption requests and notify the registrant of its decision.

If necessary, any generic questions which result from this PR Notice will be addressed in a subsequent PR Notice.

### REGISTRANT ACTION

Pesticide registrants subject to the CRP regulations should review their packages to see if they comply already, need to test their CRP, and/or need to acquire packages

that meet the new effectiveness standards and protocol test procedures by January 21, 1998.

To ensure that all registrants are in compliance with the revised effectiveness standards and protocol test procedures, **by January 21, 1998 all registrants subject to CRP (unless exempted under 40 CFR 157.24), including those whose products are currently registered with certifications on file, must submit an application for amendment (EPA Form 8570-1) and a new certification pursuant to 40 CFR 152.44 and 157.34.** The application for amendment should be marked on the **top right hand corner** in capital letters **"CRP"**.

If no change in packaging is required for compliance with the revised effectiveness standards and protocol test procedures only a new CRP certification is needed. **The CRP certification should be sent to Rosalind L. Gross** at the address given under the section for additional information. The certification should be marked on the **top right hand corner** in capital letters **"CRP CERTIFICATION NO PACKAGE CHANGE"**.

Before January 21, 1998 any new pesticide registrations subject to the CRP regulations may comply with the new effectiveness standards and protocol test procedures at the time of registration. If a registrant decides to comply **at the time of registration the CRP certification should be sent to Rosalind L. Gross** at the address given under the section for additional information. The certification should be marked on the **top right hand corner** in capital letters **"NEW CRP CERTIFICATION"**. If the registrant decides not to comply with the new effectiveness standards and protocol test procedures at the time of registration, the registrant may do so provided the product is in compliance by January 21, 1998. Then, the registrant should follow the procedures for filing an application for amendment and a new CRP certification as previously discussed.

For existing and new registrations the **new certification** should indicate:

- 1 Name and EPA registration number of the product;
- 2 Registrant's name and address;
- 3 Date and the name, title, and signature of the company official making the certification;
- 4 A certification that the product as packaged meets the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995), and that the product as packaged will continue to meet the effectiveness, compatibility, and durability standards of 40 CFR 157.32. The statement, **"I certify that the packaging**

used for this product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995)." will suffice for this purpose.

- 5 A statement describing the type of package used and its designation using the American Society for Testing and Materials (ASTM) Standard D3475-95 "Standard Classification of Child-Resistant Packages". The ASTM standard D3475-95 provides uniform terminology and universal descriptions of various types of CRP. For example, the following statement will suffice for this purpose: **"The type of package is a two piece reclosable continuously threaded closure with a random push down while turning, ASTM Type IA with a round plastic bottle and is package name A manufactured by Company B."** (Package and company name are optional). [Note: If multiple package types are involved, indicate the package sizes associated with each package type.] Copies of the ASTM Standard (copyright ASTM) are available from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428. If you have any problems in identifying the ASTM Standard D3475-95 designation for a CRP, send a sample package and inquiry to Rosalind L. Gross at the address given below.
- 6 A statement that the product must be in aerosol form or is a product that requires a metal container, and is therefore exempt from the senior adult panel test (if applicable). Specify whether the package is an aerosol or a metal container with a reclosable metal closure.

Amendment forms and CRP certifications that do not contain the aforementioned information may be returned to the submitter for the necessary revisions.

The application for amendment, EPA Form 8570-1, and new CRP certification must be sent to:

**Postal Service**

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504C)  
U. S. Environmental Protection Agency  
401 M St., S. W.  
Washington, D. C. 20460-0001

**Personal/Courier Service**

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504C)  
U. S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

**APPLICABILITY**

This PR Notice becomes effective upon the date of signature by the Agency. **All pesticides** subject to the CRP regulations and **packaged and released for shipment on or after January 21, 1998** (30 months after publication of the CPSC final rule) **must comply with the mandatory provisions of the new effectiveness standards and protocol test procedures. All registrants of pesticide products subject to CRP**



**(unless exempted under 40 CFR 157.24) must submit a new CRP certification for their products prior to their release for shipment.**

If a registrant complies with the mandatory provisions of the new effectiveness standards and protocol test procedures and submits their CRP certification to the Agency prior to the effective date (January 21, 1998), then all of the requirements specified in 60 FR 37710 July 21, 1995 will become effective. Registrants are reminded that the new CRP certification indicates compliance with all the provisions of the revised standards, 16 CFR 1700.15(b) when tested by the revised testing procedures, 16 CFR 1700.20 pursuant to 60 FR 37710 July 21, 1995.

It is a violation of 18 U.S.C. Sec. 1001 to knowingly and willfully make any false statement or representation in any matter within the jurisdiction of any department or agency of the United States. A failure to comply with the terms of 40 CFR 157.32 including the revised standards, 16 CFR 1700.15(b) when tested by the revised testing procedures, 16 CFR 1700.20 as published in 60 FR 37710 July 21, 1995 shall be in violation of FIFRA and subject to enforcement action and penalties under FIFRA sections 12 and 14.

#### **ADDITIONAL INFORMATION**

For further information about this notice please contact:

Rosalind L. Gross  
Registration Support Branch  
Registration Division (7505-W)  
EPA  
401 M Street, S.W.  
Washington, D.C. 20460  
(703) 308-8354



Stephen L. Johnson, Director  
Registration Division (7505-C)

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