METHOD FOR TESTING READY-TO-USE BAIT STATIONS WITH YOUNG CHILDREN[1]

OPP Designation: 1.229 (10-29-87)

1. Purpose

1.1 This protocol is designed to test the abilities of ready-to-use bait stations to isolate bait from children of pre-school age.

2. Rationale

2.1 Thousands of incidents of known or suspected rodenticide exposures to children under six years of age are reported each year (e.g., Litovitz and Veltri, 1985; Litovitz, *et al*, 1987). It is suspected that many more exposure incidents are not reported. This protocol has been developed to test the extent to which ready-to-use bait station designs prevent young children from being exposed to rodenticide baits.

2.2 While many reported incidents involve children under two years of age, older pre-school age children are better equipped mentally and physically to attack and compromise bait stations. Subject test ages and many other aspects of this protocol are adapted from the methods used for evaluating Child-Resistant Packaging (CRP). CRP performance standards and procedures (16 CFR §1700.15 and §1700.20) have been in use for many years. EPA has applied these methods and criteria to Child-Resistant Packaging for certain pesticides (40 CFR §157) and believes that CRP methods can be adapted for evaluating protective qualities of bait stations with children.

2.3 This protocol has been adapted from Child-Resistant Packaging test protocols developed by the Consumer Product Safety Commission (CPSC) and described in 16 CFR §1700.15 and §1700.20. The procedures described in this protocol may be modified in the future based upon knowledge gained through testing, comments from concerned parties, changes in EPA's policies, changes to CPSC methods which are appropriate for inclusion in this protocol, and other factors. If EPA determines that changes in procedures are sufficient to call into question the results of tests conducted under earlier versions of this protocol, the Agency may require the stations affected to be retested.

2.4 This protocol describes test methods that can be used with bait stations that are secured to the substrate, a wall, or other virtually immovable object and with stations that are not secured. Because young children may encounter ready-to-use bait stations in situations such as store displays, in shopping bags, in improper storage, or in improper use in which units are not secured, groups of children must be tested with units that are not secured. Testing children with secured stations also is necessary because it is possible that some designs could be more vulnerable to children's attacks when secured. Child-testing secured stations also provides a means for determining whether there are weaknesses in the securing features for a station which enable children to remove "properly secured" stations from their moorings.

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2.5 EPA will consider sequential testing of groups of 50 children as an alternative to the 200-child test. (See Federal Register, 48:13, 2389-2392.) Because the performance standards of this protocol are higher than those currently used for CRP, fewer failures can be tolerated for passing or continuing in sequential tests with ready-to-use bait stations. (See 6.3.)

3. Subjects

3.1 Use 200 healthy children, 42-51 months of age, inclusive, for the test with secured stations and 200 healthy children, 42-51 months of age, inclusive, for the test with unsecured stations. Do not use children who have had more than one previous experience in testing bait stations. Do not use the same subjects for testing secured and unsecured stations of the same design. Follow procedures outlined in 16 CFR §1700.20(a)(2) for age and sex distribution requirements for test subjects.

4. Procedures

4.1 Use production models of ready-to-use bait stations or models from early runs on preproduction molds. Do not use toxic bait in stations that are to be tested with children. Instead, use a placebo bait identical in composition and physical form to the toxic bait except for the absence of the toxicant. If the toxic bait contains a dye, the dye may also be omitted from the placebo bait formulation. To help determine whether children have contacted the bait, coat bait with a nontoxic material that will adhere to the child's skin and that will wash off easily. This material may be a visible agent or an agent that can only be detected by use of special equipment such as an ultraviolet light. Take care to apply the material only to the bait and not to areas of the bait station that are more accessible than the bait area. Inspect children's hands prior to the test to determine whether there are any materials present which could affect the reliability of the method used to determine whether the bait has been contacted. If the bait in the station is enclosed in a chamber or pouch through which rodents must chew to gain access to bait, coat the outside of the chamber or pouch with the indicator substance.

4.2 If the bait station is of a refillable design, each station tested must be subjected to simulated repeated use before it is tested with children. Prior to testing with children, each station must be opened and closed (as necessary for refilling) ten times, or more if a larger number of openings and closings would be more representative of use in the normal life of the product.

4.3 Use at least five different test sites and at least four different interviewers. Do not test more than 20% of test subjects at any one test site. No interviewer should test more than 30% of all subjects used.[2] Test children in circumstances in which they feel at ease. Do not use "hostile" or imposing test environments.

4.4 Test children in pairs. Allow each child to challenge only the station presented to him (her). Children should be on the floor or seated at a table so that the interviewer can observe them simultaneously.

[2] These stipulations regarding sites, subjects, and interviewer also hold for sequential tests.

4.5 Beginning Tests

4.5.1 For tests with unsecured stations, hand a station, free from its box or other outer packaging, to each child. A test begins when both children have been presented with stations and have been given the appropriate verbal instructions such as

> "I have just given you a box that has something in it. When I say 'Start', I want you to try to get something out of the box."

4.5.2 For tests with secured stations, present each child with a station secured using the securing method of first choice (as discussed in paragraph 4.1.2 of Protocol 1.228). A test begins when both children have been presented with stations and have been given the appropriate verbal instructions such as

> "I have just given you a box that has something in it. When I say 'Start', I want you to try to get something out of the box."

4.6 Do not encourage or discourage any specific approach by children to compromising the station unless their activities endanger themselves or each other, or involve trading stations or working together on one station. Prohibit such activities. Interviewers may gently encourage children who seem to be reluctant to participate in the test. Children may talk to each other about the stations.

4.7 Test Duration

4.7.1 If the ready-to-use station is not of a refillable design, continue the test for ten minutes. After five minutes, interviewer may remind children that they may use their feet or their teeth.

4.7.2 If the ready-to-use station is of a refillable design, suspend the test after five minutes and give the pair of subjects a demonstration, without explanation, of how to open the station. (If a special tool designed to be used with the bait station is required to open it, do not demonstrate how to open it or give the children access to the tool.) Use a separate, identical station for the demonstration. Conduct this demonstration at normal speed for opening the unit under use conditions. Do not exaggerate or protract movements. At this time, the interviewer also may remind children that they may use their feet or their teeth. After the demonstration, give subjects five more minutes to try to compromise the station.

4.8 At the conclusions of each trial, inspect child's hands, feet, mouth, clothing, and the immediate test environment for evidence of the placebo bait. Examine station carefully to determine existence and nature of any damage sustained by the unit and to assess whether bait was contacted or moved within the station by the child. If placepacks are in station, look for evidence that placepacks have been broken. Look for the marker substance (described in paragraph 4.1) on each subject's fingers, feet, mouth, and clothing.

5. Reporting Results

5.1 Report the age, sex, height, and weight of each test subject. Describe test environment and exact test procedures followed. Provide raw data sheets which indicate the performance of each test subject. Summarize the means used by children to attack stations. Describe the techniques used by each child who succeeded in compromising the station.

5.2 Report the total numbers of station failures, numbers of instances in which stations did not fail, and the percent of child-resistant effectiveness.[3] Report test results for each individual subject including whether there was a failure and the time that elapsed from the start of the test until the time, if any, that failure occurred. For refillable units, report the numbers of failures which occurred before or following the demonstration. A failure occurs when any child compromises the bait station or gains access to its contents. Examples of failures include (but are not limited to) instances in which:

a. Subject touches bait or gains access to bait in bait compartment.

b. Through any action, subject is able to move bait to an area of the station where bait can be touched by subject.

c. Subject removes bait from station.

d. Subject opens station or pulls it apart.

e. Subject cracks or breaks station with the result that the placebo bait is moved to more accessible areas or that the bait in any other way becomes more accessible to the subject.[4]

6. Performance Standards

6.1 Non-refillable Stations: Stations pass if child-resistant effectiveness is 85% or greater for the entire 10-minute test.

6.2 Refillable Stations: Stations pass if child-resistant effectiveness is 90% or greater before the demonstration and 85% or greater for the entire 10-minute period.

6.3 If sequential testing of units of 50 subjects is done, use the table below for making decisions regarding whether the station has passed or failed, or whether testing must be continued.

Sample	Sample Size	Cumulative Sample Size	Acceptance and Rejection Criteria (based upon number of failures)		
			PASS	CONTINUE	FAIL
First	50	50	0 to 2	3 to 13	≥ 14
Second	50	100	3 to 7	8 to 22	≥ 23
Third	50	150	8 to 13	14 to 30	≥ 31
Fourth	50	200	14 to 30	---	≥ 31

[3] For a 200-subject test, percent child-resistance effectiveness is calculated as "the number of children tested, less the test failures, divided by two."

[4] For this type of failure, it is not necessary that the subject touch or remove bait. For example, if the subject put a big hole in the unit, the station would fail, even if the subject did not reach in for the bait immediately or at all.

7. References

Litovitz, T.L., Martin, T.G., and Schmitz, B. (1987) 1986 annual report of the American Association of Poison Control Centers National Data Collection System. American Journal of Emergency Medicine, 5, 405-445.

Litovitz, T.L. and Veltri, J.C. (1985) 1984 annual report of the American Association of Poison Control Centers National Data Collection System. American Journal of Emergency Medicine, 3, 423-450.