METHOD FOR TESTING READY-TO-USE BAIT STATIONS WITH ADULTS FOR FACILITY OF OPENING, RECLOSING, AND SECURING[1]

OPP Designation: 1.228 (10-29-87)

1. Purpose

1.1 This protocol is designed to assess the reliability with which untrained adults can perform tasks necessary for proper use of ready-to-use bait stations.

2. Rationale

2.1 Thousands of incidents of known or suspected exposures of nontarget organisms to commensal rodenticides are reported each year. It is suspected that many more exposure incidents are not reported. Most known nontarget rodenticide exposures involve children under six years of age and dogs (c.f., Buck, et al, 1985; Litovitz, et al, 1987; Frantz, *et al*, 1984). Most exposures appear to result from use of rodenticide products that are bought almost exclusively by persons who are not professional pest control operators (NCPCC, 1970-1982). Data developed in a survey of "private" pesticide users indicate that many people do not read pesticide labels for information related to how products should be used in pest control and steps to be followed to limit hazards associated with using pesticides (Savage, et al, 1980). Whether consumers read use directions is beyond the control of the registrant and the EPA, but whether persons who read directions can and will follow them could be related to the clarity of the directions and the complexities of the tasks required.

2.2 Ready-to-use bait stations have been developed to provide homeowners and other private users of rodenticides with products that can be applied without touching or measuring bait. Whether use of such stations will lead to a safer use environment when bait is applied in areas accessible to children or nontarget animals depends upon the protective qualities of the stations and the likelihood that applicators will use the stations properly. Nearly all of the bait stations developed to date could have bait shaken out of them if they were lifted. This problem exists even for ready-to-use bait stations designed to hold paraffinized blocks because these blocks tend to crumble or break somewhat after rodents have begun to feed on them. The shake-out problem can be avoided if the bait station is secured, or otherwise immobilized, while in use. If users do not secure stations adequately or ignore directions to do so, bait shake-out could occur.

2.3 Some ready-to-use bait station designs cannot be refilled and must be discarded after the initial quantity of bait contained in them has been eaten. Other ready-to-use bait stations are refillable. Whether a refillable unit will remain as protective as it was when first packaged depends upon the durability of the unit and on the likelihood that users will reclose it properly.

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2.4 This protocol consists of two different methodologies: a test to be used for non-refillable ready-to-use bait stations and a test to be used for ready-to-use bait stations that are designed to be refillable. Select the methodology appropriate for the type of station to be tested. These procedures should be used for testing ready-to-use bait stations with "parent-aged" adults (18-45 years) and "grandparent-aged" adults (60-75 years). Adult effectiveness requirements are similar for both age groups. (See 4.3 and 5.3.)

2.5 This protocol has been developed 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 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.

3. Subjects

3.1 For the "parent-aged" tests, use 100 healthy adults, 18-45 years of age, who have no obvious physical or mental handicaps. Seventy percent of the test subjects shall be females. Within each gender, numbers of subjects used shall be approximately equal for the age ranges 18-27 years, 28-36 years, and 37-45 years.

3.2 For the "grandparent-aged" tests, use 100 healthy adults, 60-75 years of age, who have no obvious physical or mental handicaps. Seventy percent of the test subjects shall be females. Within each gender, numbers of subjects used shall be approximately equal for the age ranges 60-64 years, 65-69 years, and 70-75 years.

4. Test for Non-Refillable Stations

4.1 Procedures

4.1.1 Use at least three different test locations and at least three different interviewers.

4.1.2 Direct subjects to use the method of first choice for securing stations. The method of first choice must be one of the securing methods mentioned in the product literature. If all materials needed to secure a station by a particular method are shipped in the box with the station, that method shall be considered to be the method of first choice and shall be the method tested. If all necessary materials are not shipped in the box for any of the securing methods mentioned on the label, the manufacturer shall select the method of first choice. Provide subjects with all items (tools, nails, screws, etc.) needed for securing station by the method of first choice, if these materials are not provided with the product.

4.1.3 Test subjects individually. Give subjects the printed instructions for putting the bait station into use that are intended to appear on the package to be delivered to the consumer. If available, use the printed product label. Give subjects limited instructions such as

"When I say 'Begin', you will have 30 minutes to place this station into use and secure it according to the instructions for (the method of first choice) on the package. Indicate when you have completed the job by saying 'Done.'"

4.1.4 Allow each trial to continue for 30 minutes unless subject indicates that she or he is finished at an earlier time.[2] Record the amount of time taken from the start until
subject is finished, the amount of time that the subject appears to spend reading directions, and what the subject does with the unit.

4.1.5 After the subject is finished, determine whether the unit has been secured properly (i.e., that the method of first choice for securing the station has been executed in accordance with label directions). Note any shortcomings (e.g., failure to use the required number of screws, failure to apply tape at the required number of locations, failure to move tabs to the point where they "catch", etc.). Determine whether tasks necessary for proper use, aside from those associated with securing the unit, have been performed properly.

4.2 Reporting Results

4.2.1 Report number of persons tested, the gender and age of each subject, the securing method of first choice (and the rationale for selecting it), the time taken for each individual to secure the unit and put it into use, the amount of time that the person appeared to devote to reading directions, and what the subject did with the unit. Summarize results for the entire group and for each sex. Provide tables summarizing results and copies of all original raw data sheets.

4.2.2 Report adult failures for each sex and for all subjects together. Describe each adult failure in detail. Examples of failures include, but are not limited to, the following events:

a. The subject makes no attempt to secure the station.

b. The subject "gives up" after failing to secure the station.

c. The subject does not secure the station properly or completely.

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[2] Although 30 minutes are allowed for this test, the time required to secure stations could vary greatly depending upon the tasks that subjects are required to perform. Experimenters desiring to fix test durations to facilitate the scheduling of subjects may employ a pilot test to estimate the longest time that subjects will require before they either have secured the station of have abandoned efforts to do so. A pilot test shall include 20 "grandparent-aged" subjects, 13-15 of which shall be female. Run the subjects through the procedures prescribed in the protocol for this test. Record times, in seconds, to completion or resignation for each subject. Calculate the mean and standard deviation for test durations for the group. The duration of the main test may be limited to the nearest (or most convenient) whole number of minutes that is more than two standard deviation units beyond the mean time, in seconds, for completing the pilot test and more than 60 seconds beyond the longest test duration observed in the pilot test. Report results of pilot test separately from the results of the main 100-subject tests.

d. The subject damages the station while attempting to secure it, making securing impossible or making the bait potentially more accessible to children or nontarget animals.

e. The subject does not put the station into proper use (i.e., fails to perform acts, apart from securing, that are required for proper use).

4.2.3 Calculate and report the level of effectiveness for the test and for each sex. The level of adult effectiveness is the percent of adults who successfully secure the bait station and put it into proper use.

4.3 Performance Standards

4.3.1 90% or more of "parent-aged" test subjects must secure stations adequately as defined in paragraph 4.1.5 and put them into use properly.

4.3.2 90% or more of "grandparent-aged" test subjects must secure stations adequately as defined in paragraph 4.1.5 and put them into use properly.

5. Test for Refillable Bait Stations

5.1 Procedures

5.1.1 Use at least three different test locations and at least three different interviewers.

5.1.2 Test subjects individually.

5.1.3 Use placebo bait instead of the toxic bait. The placebo shall be identical 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.

5.1.4 To test subjects' abilities to secure stations and put them into use, follow procedures outlined under 4., the test for Non-Refillable Stations. Follow all procedures in that method including determining time required to compete the test, evaluating the quality of the job performed, determining whether the subject has passed of failed, and completing all data recording requirements associated with the individual subjects.

5.1.5 Evaluate the quality of the securing and putting into use. (See 4.1.5 and 4.2.2.) If station has been secured and deployed properly, the same station may be used for the "refilling" portion of the test. If station has not been secured and put into use properly, the subject has failed already and does not have to be tested further. Provide tools (if any) needed to open, refill, reclose, and/or resecure (using the method of first choice as described in paragraph 4.1.2) the station in accordance with the product label. (Note: It may be possible to refill some stations without removing them from the "secured" condition.) Provide safety gloves if required by the label.

5.1.6 Give subjects the printed instructions for opening, refilling, reclosing, and resecuring bait station that are to appear on the package when delivered to the consumer. If available, use printed product label. Subjects may be given limited verbal instructions such as

"When I say 'Begin', you will have 30 minutes to open this station, remove bait, replace the old bait with new bait, reclose station, and resecure it (if necessary). Indicate when you have completed the job by saying 'Done.'"

5.1.7 Allow each trial to continue until the subject indicates that she or he is finished or until 30 minutes have passed (whichever comes first).[3] For each subject, record the time taken from the start of the refilling phase of the test until the subject is finished, the time spent in reading (or appearing to read) use directions, the time taken to open the station, the time taken to remove the old bait and to refill the station, the time taken to reclose the station, and the time taken to resecure the station (if necessary). Describe the general methods used by each subject while attempting to refill the unit.

5.1.8 After the subject is finished, evaluate the quality of the refilling, reclosing, and resecuring. Examine the unit and determine whether it has been closed properly (e.g., with all tabs in proper slots), it has been locked properly, and all bait added is confined to the appropriate places (e.g., bait hoppers) within the station. If resecuring is necessary, assess the quality of the effort at resecuring the station. (See 4.1.5 and 4.2.2.) Note any failures to execute the required activities properly and completely.

5.2 Reporting Results

5.2.1 Report number of persons tested, the gender and age of each subject, and the time taken for each individual to secure and put the station into use. Report the times taken by each individual to complete the entire refilling and resecuring job, and the times taken by each individual to do each of the following activities: to open the unit, to remove the old bait, to refill the unit, to reclose the station, and to resecure it (if necessary). Report the amount of time that the person appeared to devote to reading directions for the securing and for the refilling phases of the test. Report the methods used by each subject while attempting to refill the unit. Summarize results for the entire group and for each sex. Provide tables summarizing results and copies of al original raw data sheets.

5.2.2 Report all failures for each sex and for all subjects together. Describe each adult failure in detail. Examples of failures include, but are not limited to, the following events:

a. The subject fails to secure the station or to put it into use properly. (See 4.2.2.)

[3] Experimenters desiring to fix test durations to facilitate the scheduling of subjects may employ a pilot test to estimate the longest time that subjects will require before they either have refilled and resecured the station of have abandoned efforts to do so. A pilot test shall include 20 "grandparent-aged" subjects, 13-15 of which shall be female. Run the subjects through the procedures prescribed in this protocol for the "Refill" test. Record times, in seconds, to completion or resignation for each subject. Calculate the mean and standard deviation for test durations for the group. The duration of the main test may be limited to the nearest (or most convenient) whole number of minutes that is more than two standard deviation units beyond the mean time, in seconds, for completing the test and more than 60 seconds beyond the longest test duration observed in the pilot test. Report results of pilot test separately from the results of the main 100-subject tests.

b. The subject is not able to open the station.

c. The subject damages station while attempting to open, empty, refill, reclose, or resecure it.

d. The subject spills bait while refilling station and fails to clean it up.

e. The subject puts bait in areas other than the bait hoppers.

f. The subject fails to reclose bait station completely (including locking, if necessary).

g. The subject fails to resecure station (if necessary).

h. The subject abandons efforts before entire job is completed.

i. The subject does not complete all required tasks within allotted period of time.

5.2.3 Calculate and report the level of effectiveness for the test and for each sex. The level of adult effectiveness is the percent of adults tested who successfully and properly complete all of the tasks associated with refilling the bait station and returning it to proper use.

5.3 Performance Standards

5.3.1 90% or more of "parent-aged" test subjects must secure, put into use, refill, reclose, and resecure stations adequately and return them to use.

5.3.2 90% or more of "grandparent-aged" test subjects must secure, put into use, refill, reclose, and resecure stations adequately and return them to use.

6. Post-Test Interviews (Optional)

6.1 After the test period is over, the interviewer may ask the subjects questions concerning the ease or difficulty of the tasks that they were required to perform. The post-test interview should be structured so that the subjects give these opinions first, before they are asked more "loaded" questions such as whether they would take as much time with the units if they were not being tested or whether they would buy the product if they had a rodent problem.

7. References

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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, 5:5, 405-445.

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