Report on PPPA Protocol Testing of Button Battery Packaging

June 2019

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Executive Summary

The report titled, "Summary of PPPA Protocol Testing of Button Battery Packaging," presents the findings of research conducted by the Great Lakes Marketing, under Contract 61320618P0059.

The International Electrotechnical Commission (IEC) CD 60086-4 has adopted a mechanical test method for battery packaging, originally created by the Battery Association of Japan. Staff sought to evaluate the interaction of children using 16 CFR part 1700 with four specific battery packages to discover whether the child's interaction was similar to the IEC method. Note that button batteries are not required to meet Poison Prevention Packaging Act (PPPA) packaging requirements under 16 CFR part 1700; however, the ANSI C-18 Portable Dry Cells & Batteries Committee balloted language requiring packaging designs to meet the criteria issued under PPPA. The findings suggest that, although there is an overlap between the actions children performed and IEC mechanical tests, outcomes may be different for certain packaging types. The findings also suggest that further research is needed to determine whether plastic film packages are appropriately addressed in the IEC test method.

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Introduction

Background

Lithium button batteries have caused serious injuries and deaths after ingestion by children. This has encouraged manufacturers to increase the safety features of batteries with voluntary standards. The American National Standards Committee C18 on Portable Cells and Batteries is considering several safety measures, including a required safety warning, visible icon, and placing the batteries in child-resistant packaging, tested according to the CPSC's Poisoning Prevention Packaging Act (PPPA) protocol at 16 CFR § 1700.20. Packages are given to children to try to open for two 5-minute sessions. To pass this testing, 80 percent of children must not be able to open the package after both sessions (*i.e.,* 10 minutes). Recently, the International Electrotechnical Commission (IEC) TC 35, responsible for IEC 60086-4, introduced a mechanical test for determining that battery packages are difficult for children to open.[1] This test was originally created by the Battery Association of Japan and consists of several cycles of bending, twisting, and tearing the package. This led to the development of a new package type, designed to pass this mechanical test (although not currently available on the U.S. market). CPSC staff believed that it was important to determine how a child interacts with a battery package, to observe whether it was similar to the method used in the mechanical test. Children were observed under the parameters of 16 CFR § 1700.20.

Methodology

Under Contract CPSC 61320618P0059, Great Lakes Marketing recorded the interaction that children have with the battery packaging. A total of 100 children were tested in pairs with the battery packages. Children were selected from schools and childcare centers located in a tri-state area around Toledo, OH, as well as from parents who self-selected to allow their children to participate in research studies. The schools' student population includes a mix of socio-economic groups that reflect the tri-state area. The children were randomly assigned to test one of the four packages. The panels were balanced, based on age and gender, and reflect the sample composition, as defined in the regulation. Children were between the ages of 42 months and 51 months, and there were 51 males and 49 females tested. Tables 1 and 2 demonstrate the breakdown by age and gender. The children were placed side by side, given the batteries, and asked to open them. They were monitored and redirected for 5 minutes, as needed. At the end of 5 minutes, the children were asked to take a small break, and the batteries were taken from them. The timer was reset and the batteries were given back to the children for an additional 5 minutes. If the child opened the package and separated the battery, the battery was immediately taken away from the child, and the time of opening was recorded. All interactions the child had with the packaging were also written down after the testing concluded. The children were not encouraged to use their teeth (as is done in PPPA testing); however, if a child spontaneously used their teeth, they were not discouraged.

[1] **IEC 60086-4:2019** Primary batteries - Part 4: Safety of lithium batteries, IEC: Geneva, Switzerland.

Table 1: Age Distribution of Participants

Age in months	Total (participants)
42-44	**22**
45-48	**46**
49-51	**32**
Total (participants)	**100**

Table 2: Gender Distribution of Participants

Gender	42-44 months	45-48 months	49-51	Total (participants)
Male	10	19	22	**51**
Female	12	27	10	**49**
Total (Participants)	**22**	**46**	**32**	**100**

Four different battery packages were tested. The first two were available in the U.S. marketplace. The first was a five-part, tear-off package in which a single battery tear off-was tested. It consisted of a molded plastic front fused to a cardboard back, and the battery size was CR2032. The battery was set off to one side of the package. The second package was a hard-molded plastic front fused to a foil/plastic backing. This package contained two batteries, had a hang hole on the top, and the battery size was CR2032. The third and fourth packages were only available in the Japanese marketplace, and consisted of a folded plastic film with a heat seal in the middle. There were hang holes on the top, and on the back of one was a plastic flap. Each package contained one battery size CR2016.

The batteries were discharged below 1.5 volts per cell prior to testing them with children to avoid any injury. The 1.5 volts was chosen to provide a reduced or safer level of hydroxide if the cell became lodged in a child's esophagus. This was accomplished by applying a short between the positive and negative terminals of the coin cell for greater than 2 weeks. Two push pins were used to poke small holes in the packaging, while a clothes pin and spring-loaded jumper wires were used to short the cells.

Results

Children used various methods to gain access to the battery, including bending, folding, and twisting the package multiple times, picking at both the front and back of the package, trying to peel pieces from the front or back of the package, tearing with a pincher grasp, and sometimes using their teeth.

Package A

Package A is described as folded plastic film heat-sealed on all four sides. The back of the package has a clear plastic flap and contained one loose battery size CR2016.

Twenty four children tested Package A. Seven children were between 42-44 months of age, 10 children were between 45-48 months of age, and seven children were between 49-51 months of age. Nineteen children (79%) were able to open the package, 5 children (21%) did not. Fifteen of the children

successfully opened the package within the first 5 minutes of testing. Table 3 shows the number of children that opened Package A by age group.

Table 3: Package Accessibility results for Package A categorized by Age Groups of Children

Age Groups	Package A		
	Opened	Could not open	Total
42-44 months	6	1	7
45-48 months	7	3	10
49-51 months	6	1	7
Total	19	5	24

To open package A, many children pulled on opposite ends of the package, including pulling after inserting their finger into the hole used for retail store display. Another popular method was to pick and peel at the plastic edges, sides, back, and front of the film. They also picked and peeled at the film layers around the hole area. They tried to tear the edges and sides of the package. Children sometimes twisted and pulled or folded the package. Some children pushed or pulled at the battery through the film, and also used their teeth (Figure 1). Note that Figure 1 below shows the total number of multiple actions children exhibited to attempt to open package. This applies to all figures for Packages B through D as well.

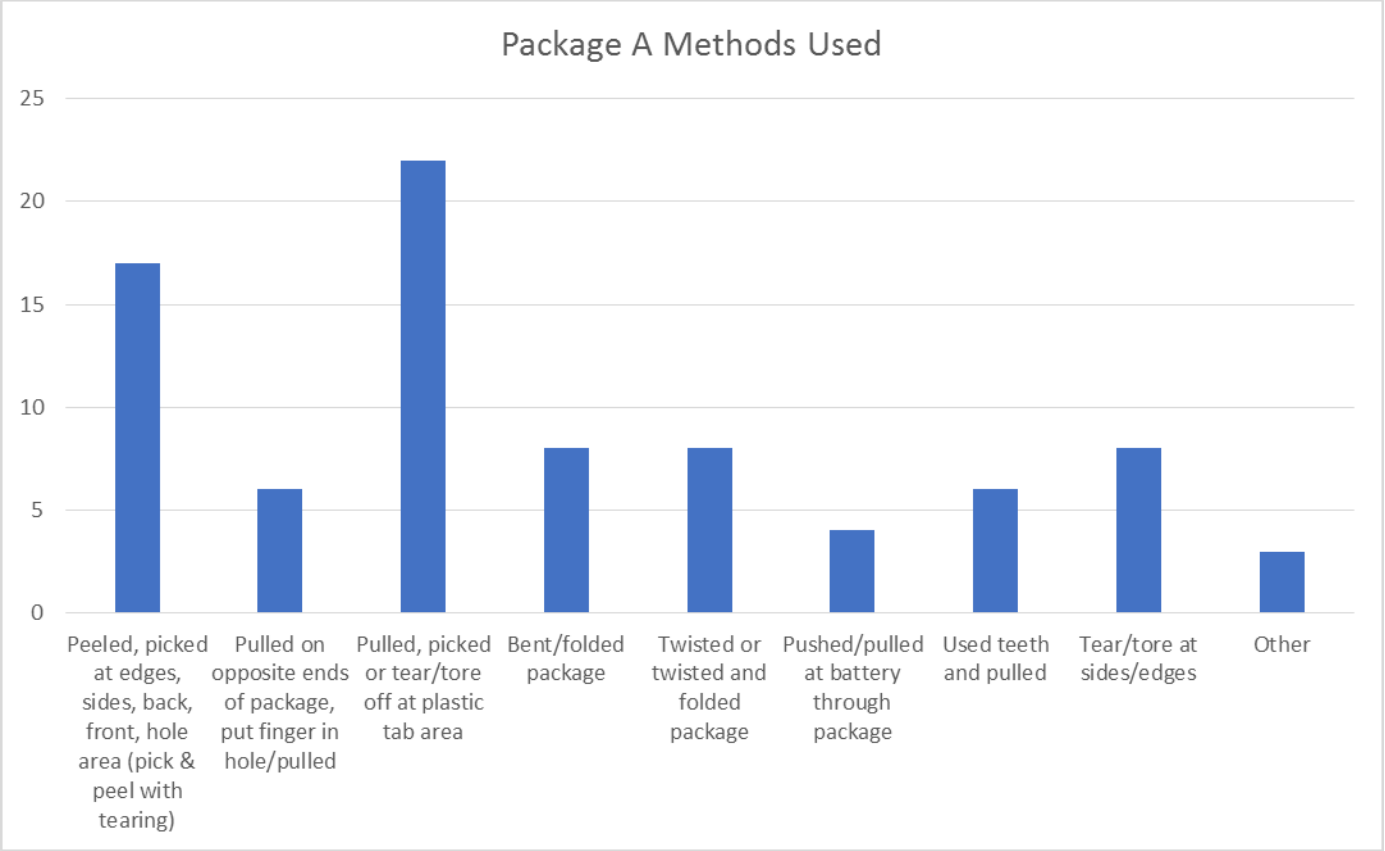

Figure 1. Methods used by Children, results of Package A

Package B

Package B consisted of five perforated sections. Children were given one section containing one battery. The package consisted of a molded plastic front fused to a cardboard back and the battery size was CR2032. The battery was secured in a fixed area.

Twenty four children tested Package B. Seven children were between the ages of 42-44 months, 10 children were between 45-48 months of age, and seven children were between 49-51 months of age. Thirteen (46%) were able to open the package, 11 (46%) did not (Table 4.) Of those children who were able to open, 10 did so in under 5 minutes.

Table 4: Package Accessibility results for Package B categorized by Age Groups of Children

Age Groups	Package B		
	Opened	Could not open	Total
42-44 months	1	6	7
45-48 months	5	5	10
49-51 months	7	0	7
Total	13	11	24

Methods used by children to access the battery in package B included folding or bending the package. This typically occurred at the corners of the package or where the plastic met the cardboard. Children picked at and peeled, or tore at the cardboard material at the edges and back of the packaging. A few children picked, pulled, or pushed on the plastic covering the battery. Three children used their teeth as a means of accessing the battery (Figure 2).

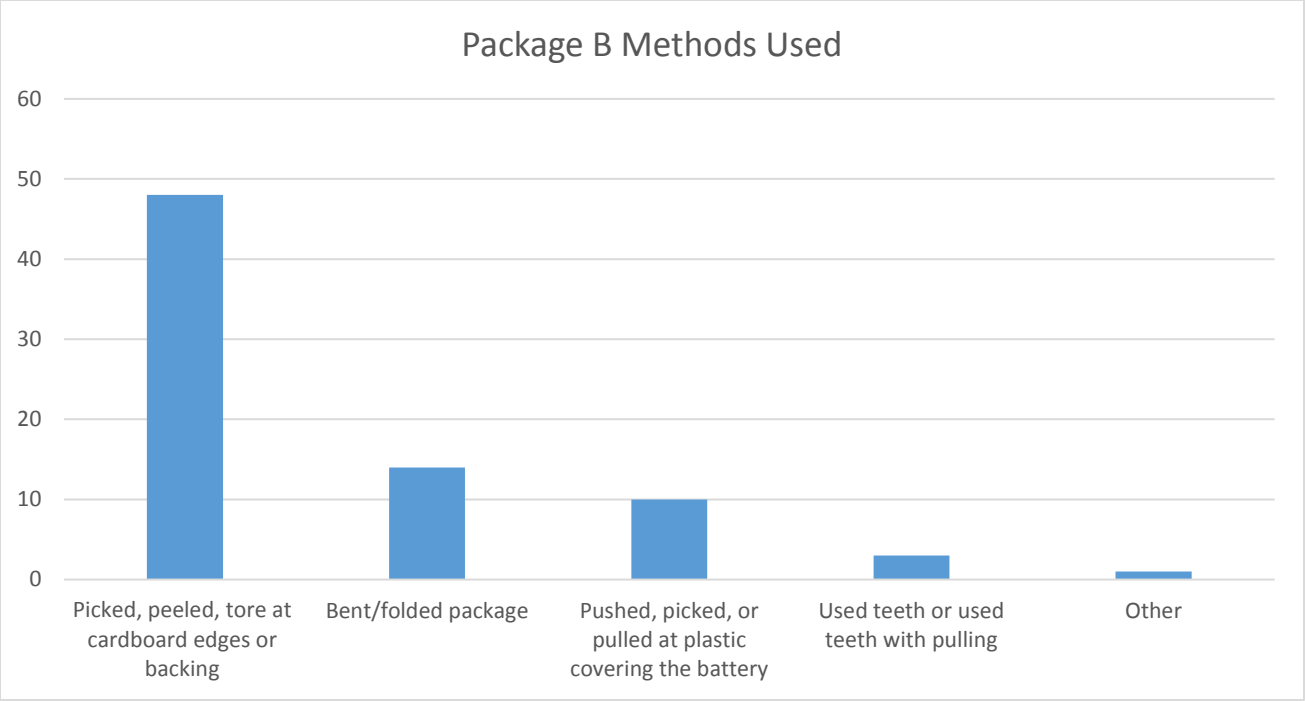

Figure 2. Methods used by Children, results of Package B

Package C

Package C was a hard molded plastic front fused to a foil/plastic backing. This package contained two batteries, had a hang hole on the top, and the battery size was CR2032.

Twenty six children tested Package C. Five children were between the ages of 42-44 months, 14 children at 45-48 months, and 7 children at 49-51 months. None of the children could open package C and access the battery (Table 5).

Table 5: Package Accessibility results for Package C categorized by Age Groups of Children

	Package C		
Age Groups	Opened	Could not open	Total
42-44 months	0	5	5
45-48 months	0	14	14
49-51 months	0	7	7
Total	0	26	26

Folding and bending was a popular method used by children to attempt to access the battery in package C. Children also picked and peeled at the sides, edges, and the plastic front or foil backing. Similar to Package A, Package C had an opening used for hanging on a retail store display. Children inserted their finger into this space and used it for leverage when pulling. A few children used their teeth and/or asked for scissors. Other methods included a combination of twisting, pulling, and bending (Figure 3).

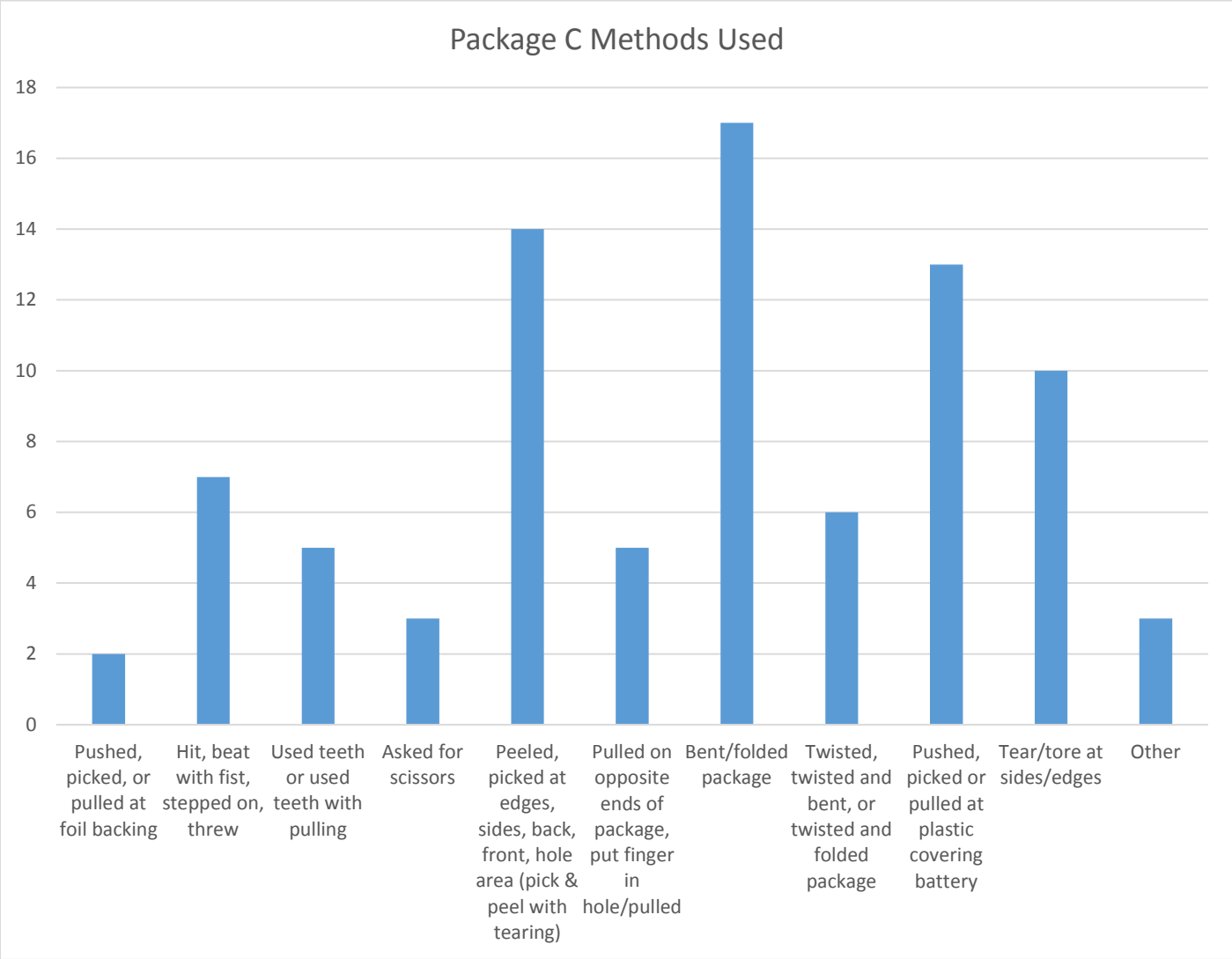

Figure 3. Methods used by Children, results of Package C

Package D

Package D consisted of a folded plastic film heat sealed on all four sides and in the middle. The battery is loose inside the package.

Twenty six children tested Package D. Three children were age 42-44 months, 12 children were age 45-48 months, and 11 children were age 49-51 months. Four children (15%) were able to open the package,

22 (85%) did not (Table 6). One child was able to open the package in less than 2 minutes, while the remaining three took between 6 and 7 minutes to open.

Table 6: Package Accessibility results for Package D categorized by Age Groups of Children

Age Groups	Package D		
	Opened	Could not open	Total
42-44 months	0	3	3
45-48 months	1	11	12
49-51 months	3	8	11
Total	4	22	26

Many children tried to open package D by using their teeth, picked and peeled at the plastic edges, sides, and front or back of the film. This action often included the child trying to pick or peel at the layers of plastic around the hole used for hanging the package at a retail store. Other methods used by children were twisting, folding, and tearing (Figure 4).

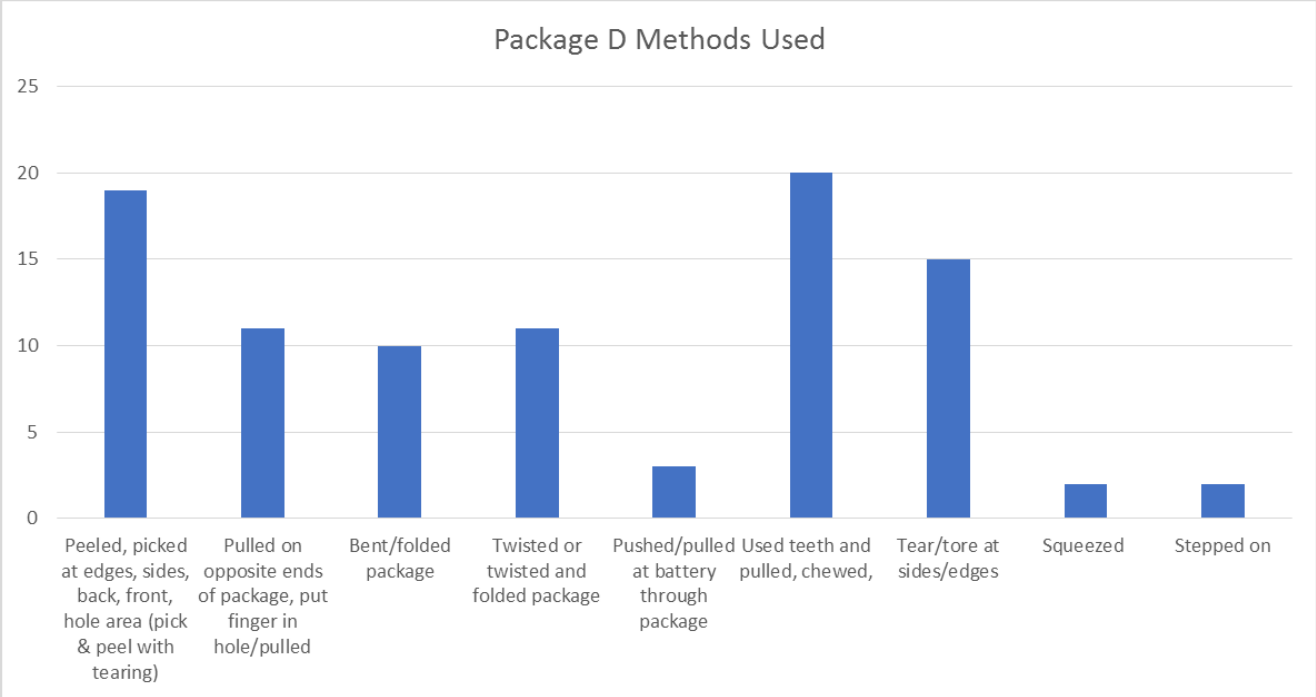

Figure 4. Methods used by Children, results of Package D

Summary of All Four Packages

Tables 7 and 8 summarize children's ability to access a battery by package type and duration between the two test intervals.

Table 7: Battery Packaging Accessibility by Number of Children

Package	Accessed battery	Did not access battery
A	19 (79%)	5 (21%)
B	13 (54%)	11 (46%)
C	0 (0%)	26 (100%)
D	4 (15%)	22 (85%)
Total (Participants)	36	64

Table 8: Battery Packaging Accessibility by 5 Minute Intervals

Package	Opened within 5 minutes	Opened after 5 minutes, before 10.	Did not open
A	14	5	5
B	9	4	11
C	0	0	26
D	1	3	22

Discussion and Conclusion

Implications

The IEC test method uses a test procedure involving bending, twisting, tearing, and pushing the battery from the package in a specified sequence. This method was developed based on a behavioral analysis of children in Japan requested to open coin cell packaging.

Staff conducted an internal study using 11 button cell packages currently available on the retail market and applied the IEC testing procedure to attempt to open the packages.

Two of the packages that staff tested were also included in the subject study (Packages B and C). Staff was able to open Package B using the IEC protocol. Fifty-four percent of children were also able to open Package B. This suggests that the results of IEC test protocol and child panel testing are similar for this particular package.

Staff was also able to open package C using the IEC protocol; however, none of the children could open it in the subject study. The test protocol, as mentioned previously, uses a method of sequential repetitive tests. In the subject study, children's actions were not as repetitive, more creative, and often included two simultaneous actions.

Staff did not test Packages A and D per IEC protocol because staff did not have access to those samples in a timely manner to include in staff's testing. It is staff's understanding that Package D complies with the Battery Association of Japan's test protocol. However, children's testing showed that four out of 26 (15.4%) children were able to open the package. Staff believes that further investigation is needed to appropriately address plastic film packages in a mechanical test protocol.

Limitations

This study is subject to several limitations. The first is the small sample size of children used to test each battery package. Protocol based on the PPPA allows for one child to test only two packages, typically 50 children per sample. Staff was limited to a 100 child panel and opted to collect data using four different types of packages, rather than limiting the test to only two package types. A larger sample size may help reduce marginal results received with using a smaller sample. The second limitation concerns the number of packages tested. Two of the packages were not available in the U.S. market. Thus, only a limited number of samples could be secured for the child testing panel. Staff was not able to test this packaging in its internal study using the IEC test protocol. Finally, the sample of children tested is not a nationally representative sample; thus, results are not generalizable to children nationally.