

CPSA 6 (b)(1) Cleared

X 3/2/94
No. 111/Prv'l. b'rs 6r

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LOG OF MEETING

SUBJECT: ASTM D10.31 Child Resistant Packaging Committee Meeting on voluntary standards as they relate to child resistant packaging.

DATE OF MEETING: 02-15-94

PLACE: ASTM Headquarters, Philadelphia, PA.

LOG ENTRY SOURCE: Charles J. Wilbur, HSPS *gpc*

COMMISSION REPRESENTATIVES: Charles J. Wilbur, HSPS

NON-COMMISSION REPRESENTATIVES:

ASTM D10.31 Members. (See ASTM meeting summary for list)

SUMMARY OF MEETING

This was a special meeting to review CPSC's Protocol Revisions Briefing Package on Child Resistant Packaging Test Data. See attached minutes for summary. The committee is considering commenting on the the Briefing Package, requesting a 180 day comment period, and requesting a chance for an oral presentation.

Hugh Lockhart and the ASTM testing through ISR was mentioned in the video.

4. Ed Saylor asked the attendees to cite the issues of concern regarding the proposed protocol changes. They are listed as follows:

- a. The need for the use of consent forms in the child testing
- b. Senior adult instructions
- c. Reclosing for child testing (when?)
- d. Encouragement to children
- e. Comment period - extension
- f. Adults can only test twice
- g. Torque for securing the packages for 72 hours for child packages
- h. Unit packages - opening definition
- i. Oral presentation to the CPSC
- j. Status of current packages regarding the new protocol
- k. Senior sites indicated by zip code in the CPSC study
- l. Senior pass for 100 panelists is cited as 95.1% successful versus 90% in the original proposal
- m. Senior adult age distribution - can the two lower age groups be combined?
- n. Availability of test agencies for all the studies

It was brought out that during the staff presentation to the commissioners by the commission chairman, that 30 days was not enough for a comment period, so they may vote for at least a 60 day comment period. Further, commissioner Mary Gall wanted time for disabled groups to review the proposed changes.

5. Ed Saylor indicated that his opinion is that we should notify the CPSC that 30 days is not enough to review the information presented and that an extension giving us enough time to gather our comments and formally reply in the ASTM consensus manner. In addition, it appears that an oral presentation to the commission would be appropriate.
6. An extensive discussion was carried out regarding child consent forms and their impact on the testing.

It was generally agreed that the need for the use of consent forms would:

- Increase the cost of testing
- Extend the time necessary to complete a test and
- Reduce the base of children available to conduct the testing

Chuck Wilbur and Suzanne Barone maintained that they have to use consent forms in their studies because they are required to according to The Use of Human Subjects regulation. Since they were adhering to our requests on how they conduct their testing, they included the use of the consent form in the revised protocol.

The question then arose about the effects of consent forms on the results of the test. Are different results obtained when consent forms are used versus when they are not used based upon the selection of the test population? Data to compare these test procedures should be reviewed (if it is possible).

7. Ed Saylor volunteered to write a letter to the CPSC commission requesting an extension to the comment period and also an oral presentation of comments. This was agreed upon by the subcommittee members present.

In addition to the above, the letter will cite a time line which was developed by Hugh Lockhart to justify the length of the requested extension period and mention that there are 13 items to be reviewed by the subcommittee.

The time line would be as follows:

- Collect data for all issues, plus consent form differences - 4-6 weeks (real question whether data exist on consent form differences)
- Analyze financial impact and test data for consent form differences - 4 weeks
- Write comments for ballot and prepare ballot - 2 weeks
- Minimum time for ballot - 4 weeks
- Processing time for ballot after returned - 4 weeks
- D10.31 letter to ASTM - 1 week
- Transmit to CPSC - 1 week
- Resolve negatives - 2 weeks

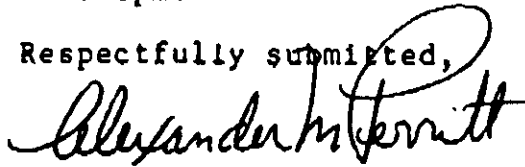
Based on the above, the committee will request a 180-day comment period (from the time of publication in Federal Register). An oral hearing after the comment period is complete will also be requested. Ed will not highlight any of the other issues in his letter.

Ed Saylor's letter will be prepared and balloted by D10.31 with a two week turnaround.

8. The preparation of comments on the major CR protocol change areas of concern were assigned to the subcommittee members as indicated below:
 - The 4 test agencies present will submit information to Bill Bradley to compile and draft comments. He will coordinate with Darla Williamson (CMA) before sending to committee.
 - Herb Snyder and Linda Walker will draft comments on senior pass level at 100 subjects.
 - Lori Dixon will draft comments for senior adult instructions.
 - Nina Johnstone will draft comments on who does reclosing packages for child testing.

- Bob and Mike Buie will draft comments on torque for securing packages for 1/2 hours for child package, and combining 2 lower age groups of senior adults.
 - Tony Carfagno will draft comments on encouragement to child and the definition of "open" for use-dose packages.
 - Perritts will draft comments on 2 tests by senior adults.
 - CSMA will try to draft comments on status of current packages vs. new protocol, and availability of test agencies to do the testing.
 - Max Kusz and Nina Johnstone will draft justification of senior site testing by zip code.
9. We will need to meet again in 6 weeks, on March 29, 8:30am - 4:30pm. After that, suggested May 24. Lexington meeting would be in addition.
10. The meeting was adjourned at 1:43pm.

Respectfully submitted,



Alexander M. Perritt, Ph.D.
D10.31 Secretary



February 17, 1994

TO: Subcommittee D10.31 on Child Resistant Packaging
D10 Executive Subcommittee

FR: Margie Lawlor, Staff Manager

RE: Enclosed Administrative Ballot

Dear Members:

Please review the attached administrative ballot and return your ballot before the deadline date. The ballot is only open for two weeks due to our tight deadline.

If you have any questions, please call me at 215-299-5518.

Margie



February 16, 1994

Chairman Jacqueline Jones-Smith
CPSC
Washington, DC 20207

Commissioner Mary Gall
CPSC
Washington, DC 20207

Dear Commissioners:

ASTM D10.31 is requesting that the written comment period for responding to the proposed revisions to the "Requirements for the Special Packaging of Household Substances" be established as 180 days from the date of publication in the Federal Register.

In addition, ASTM D10.31 is requesting that there be an opportunity for individuals and organizations to make oral presentations to the CPSC Commissioners after the 180 day written comment period has ended.

These requests are based on comments and concerns that were raised at a special ASTM D10.31 Meeting on February 15, 1994 for the purpose of discussing the proposed revisions. Twenty-six individuals were present at this meeting representing producers, users, test agencies, and governmental representatives from the CPSC and EPA.

Thirteen issues and keypoints were raised at this meeting that are a concern to industry and on which we feel comment to the Commission is important and necessary.

Of major concern is the newly added requirement that consent forms, signed by a parent or guardian, shall be obtained prior to a child's participation in the testing process. The consensus of the four major test agencies present at the meeting was that the signed consent forms would have a dramatic effect on the child testing procedure in three areas:

1. The number of children available for testing would be drastically reduced;
2. The time to complete a test would be significantly extended due to the limited availability of children;
3. The cost per test would be increased significantly due to the impact of the combined effects of #1 and #2 above.

We are requesting the 180 day written comment period to comply with the ASTM process of collecting, evaluating, and balloting our proposed comments for consensus and resolving any negative ballots:

- 6 weeks to collect, prepare, and analyze data and comments;
- 3 weeks to refine comments, review them at an ASTM D10.31 Meeting (scheduled for March 29), and prepare for balloting;
- 4 weeks to conduct D10.31 Balloting;
- 4 weeks to review and process ballot returns including a D10.31 Meeting Review (Meeting Scheduled for May 24);
- 2 weeks to resolve any negative votes;
- 2 weeks to prepare final ASTM D10.31 comments and letter for submission to the President of ASTM;
- 1 week for review and preparation of transmittal letter by ASTM President;
- 1 week to transmit letter and comments to CPSC.

ASTM D10.31 has submitted written comments and made oral presentations related to previous protocol revision proposals that were given serious consideration by the Commission and have helped to structure the current senior adult protocol proposals. Therefore, we are requesting the 180 day written comment period and an opportunity for oral presentations to again allow adequate time for industry to provide input on both the child and senior adult portions of the currently proposed protocol revisions.

Sincerely,

Edward R. Saylor
Chairman, D10.31

cc: Office of the Secretary
CPSC
Washington, DC 20207

Suzanne Barone
Directorate of Health Sciences
CPSC
Washington, DC 20207