U.S. Department
of Transportation
**Research and
Special Programs
Administration**

400 Seventh Street, S.W.
Washington, D.C. 20590

NOV 16 2000

Mr. Lawrence W. Bierlein
McCarthy, Sweeney & Harkaway, P.C.
Suite 600
2175 K Street, N.W.
Washington, D.C. 20037

Ref. No. 00-0263

Dear Mr. Bierlein:

This is in response to your September 22, 2000 letter regarding selective testing variations for packagings under the Hazardous Materials Regulations (HMR, 49 CFR Parts 171 to 180). Your request concerned the applicability of the selective testing variations found in § 178.601(g) to a packaging for a material that is toxic by inhalation.

As provided by § 173.226(c), a material that is toxic by inhalation in Hazard Zone A may be packaged in a combination packaging consisting of an inner packaging system and an outer packaging. The inner packaging system consists of an impact resistant inner receptacle packed within a leak-tight packaging. This combination packaging in turn is packed within the outer packaging. Both the inner packaging system and the outer packaging must conform to the performance test requirements of subpart M of part 178. You ask if an inner packaging system which has been tested to packing group I performance level may utilize the variations provided in § 178.601(g).

If the inner packaging system is tested in accordance with the requirements in subpart M of Part 178 and marked in accordance with § 178.503 as a UN standard packaging, then you may use the variations provided in § 178.601(g). If the inner packaging system has not been marked as a UN standard packaging, there is no provision for variations of inner packagings.

I hope this satisfies your request.

Sincerely,

Edward T. Mazzullo

Edward T. Mazzullo
Director, Office of Hazardous
Materials Standards

NOV 16 2000

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If the inner packaging system is tested in accordance with the requirements in subpart M of Part 1 and marked in accordance with § 178.503 as a UN standard packaging, then you may use the variations provided in § 178.601(g). If the inner packaging system has not been marked as a UN standard packaging, there is no provision for variations of inner packagings.

I hope this satisfies your request.

Sincerely,

Edward T. Mazzullo
Director, Office of Hazardous
Materials Standards

FACSIMILE COVER SHEET

U.S. DEPARTMENT OF TRANSPORTATION
RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION
OFFICE OF HAZARDOUS MATERIALS ENFORCEMENT
Eastern Region

820 Bear Tavern Road, Suite 306
West Trenton, New Jersey 08628

TELEPHONE: (609) 989-2256 FAX: (609) 989-2277

Date: 9/7/00 Time: _____ Number of Pages (Including Cover Sheet): 3

Send to: MR RAY WATT

Location: ALL-PAK

Fax Number: (716) 633-7745

From: CHRIS MICHALSKI

Comments: PER OUR PHONE CONVERSATION, ENCLOSED PLEASE FIND THE EXIT BRIEFING REPORT. BY ME BASED ON MY OBSERVATIONS IN JACKSONVILLE, FL. PLEASE CALL ME IF YOU HAVE ANY ADDITIONAL QUESTIONS PERTINENT TO THIS EXIT BRIEFING.

US Department of Transportation
Research and Special Programs Administration

Office of Hazardous Materials Enforcement Eastern Region

820 Bear Tavern Rd., Ste. 306
West Trenton, NJ 08628
(609)989-2256
Fax: 609 989 2277

EXIT BRIEFING

(This document is not a final report.)

Date: 9/7/00 Report Control #: 00421031

Company Name: ALL-PAK, INC

Address: 4225 GENESSEE ST, BUFFALO, NY 14225

NAME OF INDIVIDUALS RECEIVING BRIEFING:

Name: RAY WATT Title: PRESIDENT

Name: _____ Title: _____

Name: _____ Title: _____

This has been a compliance inspection conducted in accordance with Title 49 U.S.C. Section 5121(c). This exit briefing addresses only the areas noted, and it is not a finding of general compliance in any other areas covered by the Hazardous Materials Regulations that were subject to the inspection.

During the course of the inspection the following probable violations of 49 CFR and/or quality control items were noted:

PROBABLE VIOLATIONS:

Section: 178.601(d) & 173.22f(c)(2)
Explanation: CERTIFYING PACKAGES AS MEETING THE UN STANDARD FOR PIH SHIPMENTS, WHEN THE PROPER DESIGN QUALIFICATION TESTING WAS NOT CONDUCTED.
1. NOT CONDITIONED AS REQUIRED
2. INSUFFICIENT NUMBER OF SAMPLES DROPPED
3. NO INDICATION OF STACKING TEST IN THE TEST REPORT

Section: 178.503(b)(8)
Explanation: FAILURE TO USE THE NAME AND ADDRESS OR AUTHORIZED SYMBOL IN THE UN CERTIFICATION FOR PACKAGES.
(TEN-E'S CERTIFICATION USED ON A NEW DESIGN NOT TESTED BY TEN-E).

This document is not a final report. The information gathered at this inspection and any probable violations noted will be reviewed prior to finalizing the report. Probable violation(s) may be removed or others may be added during this review. In addition, quality control items may be revised to become probable violations during this review.

Upon determination that a probable violation exists, the Associate Administrator for Hazardous Materials Safety is authorized to impose certain sanctions, including warning letters, compliance orders; and civil penalties. In addition, court actions, including injunctive or criminal proceedings, may be initiated. Title 49 U.S.C. Sections 5123 and 5124 provide for civil and criminal penalties for violation of the Hazardous Materials Regulations.

A civil penalty of not more than $27,500, but not less than $250, per violation may be imposed through administrative proceedings initiated by the Office of Chief Counsel of the Research and Special Programs Administration. When a criminal violation has been determined by a court, a fine, or imprisonment for not more than 5 years, or both, may be imposed for each violation.

The inspector does not determine which sanction, if any, may be imposed and cannot provide information concerning what proceedings will be initiated or sanctions imposed.

Documentation of corrective action submitted in writing to the inspector within 30 days of the inspection may be considered for mitigation should the sanction imposed result in the issuance of a notice proposing a civil penalty. However, any documented corrective action would not eliminate or preclude the initiation of a civil penalty proceeding, a finding of violation, or assessment of a civil penalty.

The Small Business and Agricultural Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement activities. The Ombudsman will annually evaluate these activities and rate each agency's responsiveness to small business. If you wish to comment on the inspection and related activities of the Research and Special Programs Administration, call 1-888-REG-FAIR (1-888-734-3247).

I certify that I received the above briefing as it appears on this form. I understand that by signing this form I am in no way expressing agreement with its contents. I am only acknowledging that I have reviewed it and have received a copy.

Signature of Inspector(s)	Signature of Representative(s)
9/7/00	
Date	Date

U.S.D.O.T./RSPA/OHMS

Report # _____

Exhibit # _____

Page ___ of ___

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Johnsen
§173.226(c)
§178.601
Packaging
Testing
00-026

September 22, 2000

Mr. Chris Michalski
Office of Hazardous Materials Enforcement
Research & Special Programs Administration
Department of Transportation
820 Bear Tavern Road, Suite 306
West Trenton, NJ 08628

Re: All-Pak; September 9 Exit Briefing

Dear Mr. Michalski:

Thank you for the opportunity to respond to the September 9, 2000, exit briefing you sent to Ray Watt of All-Pak (copy attached). As noted in your telephone conversations with Mr. Watt, I believe there is a difference of opinion on the proper interpretation of the regulations and, by copy of this letter, I am asking Mr. Mazzullo to look at the issue.

All-Pak manufactures combination packaging for use by shippers of TIH materials under the rule applicable to them in 49 CFR 173.226(c). I first would like to note that you allege a violation of this Part 173 provision by All-Pak, and I suggest that as a packaging manufacturer the appropriate citation against the company, if any, would be under Part 178, not Part 173.

The shipper is advised under Section 173.226(c) that, for combination packagings, "both the inner packaging system and the outer packaging must conform to the performance test requirements of Subpart M of Part 178 of this subchapter, at the Packing Group I performance level."

Subpart M of Part 178 is entitled "Testing of Non-Bulk Packagings and Packages," and it covers Sections 178.600-609. Thus, it includes not only Section 178.601(c)(2), which you cite, but Section 178.601(g), which describes selective testing

variations. As I understand it, you contend that Section 178.601(g) is inapplicable, and that is our point of difference that I ask Mr. Mazzullo to address.

The situation is that All-Pak manufactures, marks, and sells a packaging for TIH shippers. This is a combination packaging consisting of the inner receptacle holding the product, a leak-tight absorbent pouch inner receptacle, a removable-head canister, a plastic bag, and padding within an outer fiberboard box. This packaging has been third-party tested by Ten-E Packaging.

One of All-Pak's customers, Dow Agro, had filled packages of this type in storage in the field. Their own people discovered that the metal removable head canister inside the filled packaging was rusting and they wanted to change it, in the field, to a unit that was not subject to such corrosion. A plastic removable head canister was considered for this purpose.

All-Pak identified a suitable plastic removable head canister of similar design to the metal unit. The company believed it would be sufficient, but before determining that this was an acceptable substitute, All-Pak performed cold drop testing on this inner canister. The results confirmed All-Pak's expectations. At the same time, All-Pak contacted Ten-E for subsequent testing of the completed packaging but the employee in charge of this project died before this work was completed.

While we acknowledge that prudence would have had All-Pack test this packaging in its entirety, that is not the same as saying that failure to have this testing performed was a violation of the regulations.

Specifically, Section 178.601(g)(1) provides a selective testing variation under which additional testing is *not* required. The conditions of this variation are important. First, the inner packagings of a combination packaging must be of similar design to the tested inner packagings. Here it was not the inner that was changed but instead an intermediate open-head packaging holding two inner receptacles, the bottle and the pouch. The canister was of similar dimensions as the replaced unit.

Second, the material of construction of the inner packagings (glass, plastic, metal, etc.) offers resistance to impact and stacking forces equal to or greater than that of the originally tested inner packaging. The intermediate removable-head unit, by All-Pak's own drop testing and their substantial knowledge of the dynamics of combination packaging, had this strength. To respond to your concerns, All-Pak since has confirmed this fact through Ten-E but, in our view, such confirmation was not required. A copy of the Ten-E retest report will be sent to you by the company under separate cover.

Third, the inner packagings had to have the same or smaller sized openings and the closure was of similar design. The innermost packaging unit and the inner receptacle (pouch) were unchanged. With regard to the removable-head canister, both units are removable head drums and, in fact, the plastic unit with a clip-on feature is more secure than the tested metal cover.

Fourth, cushioning must take up void spaces, and the expanded polystyrene pads do this. Fifth, the inner packaging orientation must be the same, and it was. Sixth, the gross mass must not exceed that originally tested, and it did not.

Under Selective Testing Variation 1, therefore, which is an integral part of Subpart M of Part 178, All-Pak did not have to test the plastic intermediate unit at all. The company did perform some tests to bolster their own expectations and subsequently All-Pak had Ten-E re- perform all the tests, but we do not agree with your characterization in the Exit Briefing that All-Pak's actions constituted "probable violations."

You make a second allegation, that the marking on the packaging was not changed. As noted above, your contention only carries weight if one concludes that Variation 1 is inapplicable and, we submit, nothing in the regulations confirms your view on this point.

In conclusion, a customer was faced with an urgent problem with packaging already filled in the field. All-Pak worked with that customer to fashion a solution to that problem. Variation 1 envisions changes to tested packagings without retesting, under certain conditions. All-Pak met those conditions. Subsequent testing by Ten-E verifies that the company's conclusions with regard to this change were valid, and that no safety issue is involved.

Therefore, we ask that you not proceed with this investigation or any subsequent penalty claim. Please contact me if you have any questions on this letter or our reading of the applicable regulations.

Sincerely,

Lawrence W. Bierlein

cc: Edward T. Mazzullo, Director
Office of Hazardous Materials Standards

Ray Watt, All-Pak