Case Study: New Package Qualification? Use "Just Right" ISTA Testing!

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PRESENTATION ABSTRACT

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PRESENTATION PAPER

Distribution Performance/Risk Assessment When Changing Packages

Inherent in the opportunity of packaging change is risk. There can be many different types of risk – negative consumer reaction to new package aesthetics, for instance. This discussion, however, will be confined to the risk of impaired package/product delivered quality (i.e. distribution damage) associated with package change and to ways of assessing that risk. Distribution damage risk assessment can be done by expert analysis, ship testing and/or laboratory simulation of distribution stress. The following is a case study where all three means of assessment were blended to evaluate the distribution "worthiness" of a proposed package change at Ross Products Division of Abbott Laboratories. Laboratory assessment of the proposed package's potential distribution performance was based on ISTA (International Safe Transit Association) methods. As with any undertaking, the methods and efforts need to be customized to the particular situation at hand. Different package changes, products being packaged, company expectations and industry norms will dictate different assessment efforts.

Background

Abbott Laboratories is a health care products company that manufactures ethical pharmaceuticals, hospital products, diagnostic test kits/equipment and nutritional products that are distributed worldwide. The Ross Products Division (RPD) of Abbott Laboratories is the nutritional products arm of Abbott. Ross Products manufactures specialty nutritional products for infants, children and adults. These include Similac infant formula, Pediasure children's nutrition, Pedialyte oral rehydration products, Ensure adult nutritionals, Glucerna diabetic nutrition and enteral tube feeding products.

The majority of Ross products are shelf stable liquids or powders. The primary packaging is a variety of steel cans, composite cans, plastic cans, glass bottles, plastic bottles, aseptic paperboard boxes and flexible pouches. The products themselves are sophisticated combinations of ingredients that are processed and packaged under tight control so that acceptable product sterility and nutrient label claim is maintained. The products and packages are subject to regulations such as the Infant Formula Act, NLEA labeling and FDA regulations. In light of this, package changes are assessed very carefully.

Case History – Club Store Package

The Opportunity of a Package Change

The package change opportunity in this case history involved two Ross Products club store packages. While the primary container (an 8 oz. can) remained the same, the secondary package was to be changed to a more up-to-date style of package. In addition to providing a more visually appealing package on the retail shelf, the package change would also provide a cost savings.

The first club store package in this case history was for the Ensure 8 oz. liquid product in a plastic can. The new package was implemented in 2001. The second club store package was for Glucerna 8 oz. liquid in a steel can. This package change was implemented in 2002.

The existing secondary package in both instances consisted of a printed corrugated tray containing 24 cans covered by a folded 3-panel printed-paper insert which was then shrink wrapped. The graphics on the printed insert (which covered the package top and 2 long sides) and on the corrugated tray (bottom and short ends) were visible through the clear shrink film. This package design was typical for many first generation club store packages.

The new secondary package retained the original printed corrugated tray but the shrink film was to be printed with graphics. The printed-paper insert would then be eliminated. This new package had a more up-to-date appearance – i.e. was more in line with the next generation of club store packages. The new package had a larger printed area and the graphics had more visual impact (the ink was on the reverse side of the clear shrink film instead of on the separate printed-paper insert underneath the film). The cost to print the film was less than the cost of a separate printed-paper insert. The printed film was automatically applied to the package in register using a servo film advance controlled by a photocell that read an eye mark on the printed film. In contrast, the printed-paper insert had to be placed onto the package by hand.

The Challenge: Assessment of Risk to Delivered Package Quality

The proposed package had to maintain acceptable integrity and appearance at point of sale. The challenge was to determine the best means of making that assessment. The best means would provide a high level of assurance for correctly characterizing long-term performance in the field but with the minimum resources expended to make that assessment. But what were the options for making the assessment?

Assessment Method Options

To correctly predict long-term package performance under distribution stress, the following tools can be used: expert knowledge/rigorous logic, actual shipment and stress simulation in the laboratory.

I. Expert Knowledge/Rigorous Logic

Expert knowledge and/or rigorous logic can help determine what testing and the amount of testing that is needed to make a robust assessment. Sometimes previous knowledge (expert knowledge) and/or rigorous logic will allow us to focus the testing of the package to a specific distribution stress (or stresses) and bypass other testing (bypass simulation of stresses that the package is not particularly susceptible to). Sometimes knowledge and logic will indicate that no distribution testing is needed – the proposed change will not encounter a problem with distribution stress. In either case, time and effort will be conserved for better uses. Note: amending or curtailing test regimens based on knowledge/logic is completely different from just making a change willy-nilly and then hoping for the best.

II. Actual Shipment (test shipment)

Actual shipment does, in fact, expose test packages to a slice of the actual distribution environment. Unfortunately it is only a small slice of the whole distribution reality because there can be large variation in distribution stress from shipment to shipment. Unless the shipment was instrumented, it may be hard to know if the shipment experienced negligible, average or unusually rigorous distribution stress. Even with multiple test shipments, the full extent of distribution stress may not be experienced by the test packages due to the large variation (shipment to shipment) of distribution stress.

III. Laboratory Simulation of Distribution Stress

Laboratory simulation of distribution stress can be conducted to assess the likely performance of the package in the distribution environment.

A. The advantages of laboratory testing include:

1. Simulated distribution stress is controlled – it is a known, definable stress input.
    a. Package performance is assessed in response to the known stress input.
    b. The type and intensity of the simulated distribution stress can be (and should be) created to replicate, as best as possible, actual distribution environment stress.

2. Simulated distribution stress is repeatable – assuming adequate test equipment and techniques.
    a. Performance of a proposed package can be compared to an existing package.

3. Laboratory testing can be completed more quickly than test shipments.
    a. Package performance assessment can be completed in hours rather than days.
    b. Packages can be modified in response to initial test results and quickly retested.
    c. Lab tests can be quickly adjusted/refocused based on preliminary results.

4. Sometimes fewer test samples can be used than with test shipments (can still get good results).
    a. Column stack vibration testing uses fewer samples vs. full pallet shipment.
    b. This can be important with limited quantities of expensive prototype products.

B. Considerations for laboratory testing include:

1. There must be access to a laboratory.
    a. Not every company has a test lab.
    b. However, many ISTA certified 3rd party testing laboratories exist around the world.

2. Does the test lab have capabilities matched to the product and distribution environment in question?
    a. Knowing the characteristics of the distribution environment in question is helpful.
    b. Knowing the basic strengths/weaknesses of the product/package is also helpful.
    c. The ISTA *Resource Book* lists the particular capabilities of each certified lab.

3. Getting test packages to the lab must be considered.
    a. Test samples can be damaged during shipment (speared by a fork lift, etc.).
        1.) Some shipment methods are better than others (private carrier vs. LTL).
    b. Test samples can be inspected and repacked - but there can be concerns with doing so.
        1.) Handling during inspection can affect the package.
        2.) Repacking the test samples may not duplicate the original package.

4. Laboratory tests may simulate parts of the distribution environment but may not exactly duplicate the distribution environment.

a. For example, closed loop computer controlled random vertical vibration on an electro-hydraulic shaker can be a very useful simulation. It does not, however, exactly duplicate the 6 degrees of freedom vibration inputs (vertical, horizontal, longitudinal, pitch, yaw, roll) encountered in actual transit.

b. Generally, the results from simulation are good enough to aid in decision-making.

5. Does the test protocol simulate the types of distribution stress and intensity of stress that the package is likely to experience in its distribution system?

a. Knowledge of distribution system being used is essential (i.e. does the product get to market via palletized shipment, small parcel or by individual floor loaded boxes?).

b. Distribution environment data collection is a means of obtaining data to more precisely characterize the type and intensity of stress in the particular distribution system in question.

1.) Transit vibration data from instrumented shipments can be summarized by PSD plots. These plots can define the random vibration test that is conducted.

2.) Drop height recorders can help generate simulated manual material handling test protocols from the combined data from many shipments.

c. If specific distribution environment stress data is not available, ISTA test methods can be used.

1.) ISTA test methods specify tests and test intensity that simulate the type of transit and material handling stress inherent for the general type of distribution system being used. For instance:

a.) 3E specifies performance tests for unitized loads of the same product.

b.) 3F is for individual packaged-products (100 lbs. or less) that are shipped non-unitized from distribution center to retail outlet.

c.) 3C is for individual packaged products (150 lbs. or less) that are shipped in parcel delivery systems.

2.) Sometimes the tester elects to modify an ISTA procedure.

a.) It might be based on expert knowledge, test shipments or other information.

b.) This would be done to get a better assessment of package performance in a specific situation.

c.) This would be useful for internal decision making rather than ISTA package certification.

d. “Just Right” testing vs. “under testing”, “over testing”

1.) “Under testing”:

a.) Not conducting tests that simulate stresses that the proposed package will in fact encounter in the distribution environment

b.) Conducting stress tests with insufficient intensity

c.) Result: unaware of potential damage problems with the proposed package

2.) “Over testing”:

a.) Conducting tests that simulate stresses not likely to be encountered by the proposed package in its distribution system

b.) Conducting stress tests with excess intensity – intensity not likely to be encountered by the proposed package in its distribution system

c.) Results:

- Can prevent implementation of a perfectly good package

- Can cause over packaging (use more packaging than needed)

3.) "Just Right" testing:
   a.) Avoids potential damage problems
   b.) Reduces over packaging – a step toward "Just Right Packaging" (no more and no less packaging than is needed)

A Combination of Assessment Methods Was Used for Club Store Package Change

A combination of assessment methods (expert knowledge/logic, test shipments and laboratory testing) was used in the qualification of the proposed 8 oz. club store pack.

The package in question is sold solely to club stores. Knowledge of the club distribution environment led to characterization as it being mainly palletized unit load movement (in transit and in warehouse handling) with some manual handling (shelf stocking at point of sale). Past experience with this type of package had shown it to be sensitive to transit vibration and to free fall drops in manual handling. Thus the assessment of the proposed package would focus on resistance to transit vibration stress and free fall drops. Since there was no recorded data of vibration and free fall drops experienced by these Ross products in club store distribution, it was decided to use the best fit ISTA test methods as the basis for simulated distribution stress testing in the laboratory.

Before simulated distribution stress testing of the proposed packages could be started, test samples had to be shipped in from the Ross manufacturing plant in Casa Grande, Arizona, to the Ross Distribution Simulation Laboratory (the Ross DSL) in Columbus, Ohio. Pallet loads of test samples were generated in packaging machinery trial runs at the Ross Casa Grande plant. As there were multiple machinery trial runs, several shipments of palletized test samples were sent to the Ross DSL in Columbus. An evaluation of the test samples upon arrival at the DSL prior to laboratory testing offered a chance to assess the effect of 2000 plus miles of truck transit vibration on the proposed package. Shipment from Arizona had minimal effect on the proposed package. By results of the test shipments alone, the proposed package would have been assessed to have acceptable performance in pallet load shipment via truck. This was not enough, however.

As previously discussed, relying solely on test shipments is risky since:
1. There can be large variation in distribution stress from shipment to shipment.
2. The character and intensity of distribution stress in test shipments is unknown (unless the test shipments are instrumented with environmental stress monitors).

These shipments were not instrumented (the stress during the shipments was unknown) and did not include the manual handling that might occur in the stocking of the shelves at the club store. This affirmed the need for laboratory testing to make a full assessment of the projected performance of the proposed package. This would give maximum assurance of acceptable delivered quality (minimize risk of unacceptable delivered quality). Laboratory testing would focus on simulated truck transit vibration and on free fall drops for manual handling simulation. Since the proposed package is shipped in pallet load quantities via truck, ISTA 3E (Performance Tests for Unitized Loads for Same Product) was selected for truck transit vibration simulation.

For the manual handling simulation, a special set of free fall drops was developed based on knowledge of the characteristics (including weaknesses) of the present and the proposed packages. From previous drop tests it was known that the most stressful drop orientations for the shrink film in the present and proposed packages were impacts to the bottom corners and bottom edges. The film was most likely to split or cans to fall out of the package in these drop orientations. In addition, bottom corner and bottom edge drops are required as part of ISTA Procedure 3F – "Packaged Products, Distribution Center to Retail Outlet Shipment, up to 100 lbs." ISTA 3F is a general simulation test for packaged-products that are shipped as an individual

package from a distribution center to a retail outlet. ISTA 3F has two sets of shock tests to simulate the free fall drops encountered in the picking, shipping and stocking of individual packages in their trip from DC to retail. Only a portion of the ISTA 3F drops was used in the testing of the proposed Ross Products package to better simulate the manual handling that these Ross products typically receive when being stocked into club store pharmacy area. Rather than being displayed in pallet load format, these Ross products are removed from the shipping pallet and placed onto the retail shelves. A drop height of 24" was selected for the free fall drops in the manual handling simulation for the performance assessment of the proposed package. This is based on the 24" drop height that is paired with the corner and edge drops in ISTA 3F.

Drop Test Results: performance in drop testing was comparable between the present and proposed package. This was the result even though the proposed package used shrink film with different tensile characteristics and thickness than the shrink film used on the existing package.

The random vertical vibration power spectral density (PSD) profile for simulation of truck transit in ISTA 3E has an overall Grms level of 0.52. Laboratory simulation using this profile produced severe scuffing of the printing ink on the proposed package. This high degree of ink scuffing had not been seen on the test product that had been shipped on several occasions from Casa Grande, Arizona to Columbus, Ohio. In addition, other club store products (soups, beans, canned fruit, etc.) using printed shrink film for multipacks of steel cans did not appear to have a problem with ink scuffing. This was based on inspection of these products in club stores. The conclusion was that the 3E profile was a probable over test in this situation (i.e. the evaluation of a secondary package). Prior testing using the 3E profile had shown the performance of the primary package (the 8 oz. can) to be acceptable.

However, if the 3E profile were used as the performance evaluation standard for the proposed printed film secondary package, the proposed package would not be implemented – with a loss of the desired attributes (improved retail shelf appearance at a reduced cost) of the new package. Expert judgment felt that the proposed package should be implemented based on ship test performance and on acceptable performance of the same type of packaging on other club store products. The only risk might be to the appearance of the packages in the top layers of the pallet rather than a threat to primary package integrity. Still there was the desire to have laboratory testing predict acceptable performance in the field based on simulated transit vibration.

The situation was reviewed with Dennis Young of Dennis Young Associates (Dennis is also an Associate Director of ISTA) during a distribution packaging test methods update conducted at Ross. Dennis suggested that we try one of the vibration profiles in ISTA 3H. The vibration profiles in 3H are based on more current and more extensive transit environment data than 3E. Of the two profiles in 3H (steel spring and air-ride), the steel spring profile was selected because it put more energy into the lading at frequencies closest to the natural frequency of the Ross palletized product. This would be a more conservative test. Ross products are shipped on trucks that can have either steel springs or air-ride suspensions.

Vibration Test Results: The vibration testing conducted with the 3H steel spring profile caused minimal scuffing of the ink on the proposed package. The laboratory vibration tests (based on 3H) now predicted that the performance of the proposed package would be acceptable in long-term distribution. Combined with the acceptable results from the drop tests and test shipments, the acceptable results from the laboratory vibration tests allowed the proposed package to be implemented.

Field Performance Matches Prediction of Laboratory Testing = Success

The proposed printed film club store package for Ensure and Ensure Plus 8 oz. (which use plastic cans) was implemented in 2001. The same type of printed film club store package was implemented in 2002 on Glucerna 8 oz. (which uses steel cans). Both packages have been successful. There have been no damage complaints and spot checks in the field have found

package appearance to be favorable. Overall visual impact at retail of the new package is much improved over the previous package. In addition, a cost reduction has been realized with the new package.

Key Learning's

It is better to test than to not test.

You gain knowledge of performance when package is acted upon (i.e., "When it was shipped, this happened. When it was dropped, that happened.")

"Controlled" testing (type/intensity of stress known) adds another dimension to the data.

You gain knowledge of package performance under a known stress.

The performance of proposed package can be compared to that of an existing package.

The correct test (type and intensity) adds yet more (valuable) information.

Use tests that simulate stresses likely to be encountered in the distribution environment in question.

-Anything transported will experience vibration.

-Individual packages may or may not be dropped – but at least some will..

Perform the best simulation of the stresses likely to be encountered.

-Closed loop, computer controlled random vertical vibration simulating a known transit environment can be very useful.

-Rotary 1" displacement vibration on a mechanical table is much less useful.

Test at intensity likely to be encountered in the distribution environment in question.

-Getting your own environmental data can be a great way to formulate a "just right" test.

Suggestion: understand the ground rules for successfully gathering environmental data

-If you can't get your own environmental data, use the latest/best industry data.

ISTA procedures can help in that regard

Data is shared at symposiums like "Dimensions" (sponsored by ISTA)

Working with experts may be helpful as well

Expert knowledge/analysis can be very helpful.

Have knowledge of the distribution system in question.

-This will help determine which distribution stresses likely to be encountered in the particular situation.

Knowledge of the product and package (strengths, weaknesses) can be very helpful

-The correct tests get conducted.

-Some tests can be eliminated so that:

The focus can be on what is relevant and

Sufficient testing can be conducted (enough tests, samples, inspections)

Knowledge of ISTA test procedures can help with conducting the best tests for the situation.

Get help from "Experts" who may have additional knowledge to apply to the situation.

Have more than one "tool" in your "tool bag".

Knowledge of the distribution environment in question, knowledge of multiple ISTA procedures, knowledge of product characteristics and the ability to apply that knowledge to a particular situation are all tools than can be used in the package change assessment process. It is much more powerful to have multiple tools and to use them as appropriate. If you have only one tool, then it gets used for everything - whether it is the best tool for the job or not (i.e." If all that you have is a hammer, then everything becomes a nail"). More tools make it easier to get to "Just Right" testing.

"Just Right" testing minimizes risk while minimizing testing effort.

Blending all the above can provide a “Just Right” test procedure to make the best assessment of the potential long term performance of a proposed package in its distribution environment - with the highest assurance (risk is minimized) of success with the minimum effort.