

**PRODUCT LIABILITY
PREVENTION GUIDE**
for
**Packaging and Processing
Machinery
Manufacturers**

Volume 1 Fifth Edition



**The Association for Packaging
and Processing Technologies**

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INTRODUCTION

Preventing product liability issues is important to every packaging and processing machinery manufacturer. Packaging and Processing machinery manufacturers can face litigation even when their machinery performed exactly as intended and requested by the customer.

Injuries can occur from any of the following, none of which is explicitly under the control of the packaging machinery manufacturer:

- Not locking out the energy sources during maintenance
- Operating procedures not being followed
- Operators not being sufficiently trained
- Improper installation of the packaging machine
- Machinery not properly maintained
- Improper system integration of machinery

Due to Worker Compensation laws, the injured worker may not sue his/her employer except in very rare situations. Thus, plaintiffs regularly seek to recover damages from the machinery supplier – warranted or not. In some instances, plaintiffs seek punitive damage awards which can involve excessive financial impacts and can threaten the very existence of the company.

The *Product Liability Prevention Guide* is now contained in two volumes. Volume 1 provides an overview of the product liability process and how packaging and processing machinery manufacturers can proactively address issues related to products liability. Volume 2 focuses on the post-sale issues related to legacy machinery.

This *Guide* assists packaging and processing machinery manufacturers with information on how to decrease their product liability exposures. There are two distinct methods to prevent problems with product liability:

- 1) Build a safe machine
- 2) Improve the ability of the company to defend itself when litigation occurs.

This *Guide* identifies actions that packaging and processing machinery manufacturers can take now before an incident occurs that might result in litigation, and also actions that should be taken once the company learns that an incident has occurred.

PMMI has developed this *Guide* to assist PMMI members in establishing and developing product liability prevention programs and policies. The *Guide* is intended to provide **general** guidelines for the development and implementation of such programs and policies. To assist readers with terminology, a glossary of terms commonly used in litigation appears at the end of this *Guide*.

The *Guide* is not the sole authority on product safety or product liability in packaging and processing machinery manufacturing, nor are all of the guidelines set forth in the *Guide* necessarily applicable to each and every product manufactured by PMMI's members. Local requirements and laws vary from state to state, and even from city to city. Therefore, PMMI encourages its members to consult with their own professional advisors in developing and implementing a product liability program that is specifically tailored to the particular products manufactured by each member. Additionally, because of the constantly evolving law concerning product liability, any product liability prevention program should be reviewed and updated on a periodic basis. This *Guide* is not and cannot be construed as specific legal advice; PMMI strongly urges that readers consult appropriate counsel in the specific jurisdiction for answers to discreet legal issues. PMMI and the contributors disclaim responsibility for any statements that may be found to be incorrect, inaccurate or incomplete, and for the omission of information that may be considered pertinent.

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AN OVERVIEW OF PRODUCT LIABILITY

Societal Approaches To Risk Reduction

Packaging and processing machinery manufacturers ship machinery all over the world into many different cultures and existing social contexts. As similar as the U.S. and European cultures are, there are distinct differences in how each society operates. Within a society, there are four primary methods to reduce risk to the members of that society:

1. The marketplace – allowing customers to select the level of safety they wish to purchase
2. Self-regulation – such as voluntary standards (ANSI, ASTM, NFPA, etc.)
3. Government regulation – such as OSHA, European Directives (laws), codes, etc.
4. Tort law – product liability litigation

Marketplace - An example of marketplace selection occurs when a packaging or processing machinery customer requests additional guards or safety devices beyond what is supplied with the base machine. Typically, the customer pays for the additional level of safety / risk reduction. This approach works well provided that the machinery manufacturer can demonstrate that the base machine provides an acceptable level of risk and that the customer's request is more than what is necessary to achieve an acceptable risk level. This is not unusual since different organizations often have different views on acceptable risk. Note that in this example the user's acceptable risk level represents a higher degree of safety, but the converse often occurs where the user removes guards or defeats safety control systems in a manner unforeseeable to the manufacturer.

Self-regulation - Self-regulation is an approach that is very common in the U.S. ANSI/PMMI B155.1 is an example that all packaging and processing machinery manufacturers and users need to review. In the U.S., self-regulation is considered an effective means to achieve acceptable risk largely because of the aggressive enforcement that occurs through tort law. In Europe the tort law enforcement role is much less aggressive and self-regulation is largely considered ineffective as a means to achieve acceptable risk as determined by that society.

Government regulation - Government regulation is considered the preferred method to set acceptable risk levels in the European Union (EU). Since non-compliance with a government regulation is a violation of law / criminal offense, the consequences of violation are increased, and compliance is considered more effective. This does not mean that violations do not occur, but the presumption in Europe is that government regulations are effective and that self-regulation is not.

Tort law - Tort law is the fourth societal method to reduce risk, and in the U.S. takes the form of product liability litigation, which is the primary focus of this *Guide*.

Why do these different approaches matter, especially to a packaging or processing machine manufacturer that ships primarily to the U.S. market? The globalization of commerce is not limited to selling machinery. Plaintiff attorneys in the U.S. will not hesitate to try to introduce non-U.S. standards if it will help them prove their case. Even though packaging and processing machinery does not necessarily need to meet the highest global requirements, machinery manufacturers need to understand the different societal approaches and be able to defend their decisions in the event of litigation.

A Basic Primer On Product Liability

Although there is no uniform body of product liability law in the U.S., each state provides some form of redress for injuries suffered because of a defective product. In many instances, this can

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include claims against any person or entity that designed, manufactured, marketed, distributed or sold the product. In many jurisdictions, those who service and/or repair a product are also potentially liable for these injuries, depending on the nature of the activity and whether it is related to the injury mechanism. In most cases, the issue of whether or not a product is defective is decided without regard to the conduct of the manufacturer. In other words, the critical focus is on the product and nothing else – the fact that the manufacturer acted reasonably and in good faith is of no consequence. This concept is known as *strict liability*. Under strict liability, plaintiff attorneys will focus the jury's attention on the machine and its alleged flaws. The manufacturer's actions, decisions, and people who made them are generally not to be considered under strict liability.

In other states, courts apply *general negligence* principles, where the conduct of the manufacturer is a consideration in assessing the manufacturer's ultimate liability for its product. Regardless, the manufacturer's ability to demonstrate that it undertook a sound, thoughtful and reasoned approach to the design of its products, incorporating safety considerations, risk assessment and the like, will be important to its ability to defend itself against any product liability lawsuit. While several states have enacted codes to address product liability issues, some continue to rely on developing case law, or "common law" to fashion their liability scheme. Given the diversity of approaches, this *Guide* will touch upon issues that are common to most jurisdictions. It is not an all-encompassing treatise on the law, but a guide to highlight general principles that may be relevant to the industry as a whole in its efforts to minimize product liability risk and produce products with acceptable risk.

A Brief History of Product Liability

Most modern liability concepts find their genesis in the Restatement (Second) of Torts, adopted in the 1960's by the American Law Institute (ALI), composed of judges and attorneys (both private practitioners and law professors). The Restatement (Second) included Section 402A, which suggested that a seller of an unreasonably dangerous product was liable to an "ultimate user" injured by that product, provided it had not been substantially altered after the sale.

Over the years, two primary tests emerged for determining whether a product was unreasonably dangerous – the *consumer expectation test* and the *risk-utility test*. Put simply, a product is unreasonably dangerous under the consumer expectation test if it was beyond the risk contemplated by the ordinary user. Under the *risk utility test*, a product is unreasonably dangerous when the risks inherent in the product outweigh the benefits (utility) of the product, as designed. The Restatement (Second) also recognized that certain products may require warnings and/or instructions in order to be considered not unreasonably dangerous.

These general concepts dominated product liability law in America for three decades. In the late 1990's, as many states began to recognize many collateral claims and defenses not expressly discussed in the Restatement (Second), the ALI adopted a radically changed Restatement (Third) of Torts. The Restatement (Third) provides three distinct types of defect which may invoke liability:

- **Design Defects:** A product is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;

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- **Manufacturing Defects:** A product contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
- **Inadequate Warnings or Instructions Defects:** A product is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

Just as with the Restatement (Second), individual states have adopted some, but not all, of the Restatement (Third). While the classifications of defect may seem a bit more straightforward than before, a manufacturer must realize that the precise definition of a defective product will vary from state to state.

The Product Liability Prevention Response

In order to face the ever-changing nature of product liability claims, today's manufacturers (of all types and sizes) have responded by placing great emphasis on preventative measures at all stages of their business. No harm, no liability. Effectively preventing or reducing product liability exposure involves two key actions:

1. Designing and building a safe machine
2. Make the company defendable

These actions are interrelated but distinct and packaging and processing machine manufacturers need to concentrate on both areas to decrease their product liability exposures.

Building A Safe Machine

A safe machine is one that has risks reduced to an acceptable level without impeding the machine's utility. Packaging and processing machinery manufacturers have a long history of meeting this requirement – even if not formally documented. Building a machine with acceptable risk involves complying with the applicable industry and government standards and using sound engineering judgment.

Complying With Industry Standards

Building a safe machine involves actions that packaging and processing machinery manufacturers can take before an incident occurs that might result in litigation.

Building a safe machine should include complying with the voluntary, self-regulatory industry standards that apply to packaging machinery.

PMMI is recognized by the American National Standards Institute (ANSI) as an accredited standard developing organization (SDO). PMMI has promulgated a standard for packaging machines known as ANSI/PMMI B155.1 *Safety Requirements for the Construction, Care and Use of Packaging and Packaging-Related Converting Machinery* since 1972. ANSI/PMMI B155.1 was developed by the Packaging Machinery Manufacturers Institute as a voluntary standard to establish safety requirements with respect to the construction, care and use of packaging and packaging-related converting machinery. The 2006 version of the standard has been harmonized

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with European (EN) and International (ISO) standards by the introduction of hazard identification and risk assessment as the principal method for analyzing hazards to personnel and achieving a level of acceptable risk.

The scope of ANSI/PMMI B155.1-2016 *Safety Requirements for Packaging and Processing Machinery* was changed to include processing machinery for food, beverage and pharmaceutical products. This change was prompted by the expansion of PMMI's membership criteria.

The requirements of ANSI/PMMI B155.1-2016 apply to new, modified or rebuilt industrial and commercial:

- processing machinery used to produce food, beverage and pharmaceutical products;
- packaging machinery that performs packaging functions for primary, secondary, and tertiary (transport / distribution) packaging;
- coordination of the packaging functions that take place on the production line; and
- packaging-related converting machinery.

This standard does not apply to packaging machinery used by retail consumers.

Packaging and processing machinery suppliers (manufacturers) and users have responsibilities for defining and achieving acceptable risk. The supplier and the user either separately or jointly identify hazards, assess risks and reduce risks to an acceptable level within the scope of their respective work activities as described in the ANSI/PMMI B155.1-2016 standard. Although the responsibilities of the supplier and the user differ over the life cycle of the packaging machinery, each uses the same risk assessment process.

All manufacturers of packaging and processing machinery should become intimately familiar with ANSI/PMMI B155.1, for failure to abide by it will often be damaging in product liability litigation.

Although the ANSI/PMMI B155.1 standard was first published in 1972, the most recent revision was released in 2016. The PMMI B155.1 committee recommended that suppliers complete and implement design changes for new packaging and processing machinery within 6 months of the publication of the standard.

Most packaging and processing machinery manufacturers have a long and successful history of building safe machinery. Part of this history has included complying with prior versions of the ANSI/PMMI B155.1 standard.

All packaging and processing machinery manufacturers need to review the new requirements of the 2016 edition of ANSI/PMMI B155.1. This version of the standard includes changes and "doing what you always did" may not comply with the new requirements, particularly the requirements for performing risk assessments and documenting that an acceptable level of risk has been achieved.

Acceptable risk is defined in the standard as:

acceptable risk - risk that is accepted for a given task or hazard. For the purpose of this standard the terms "acceptable risk" and "tolerable risk" are considered synonymous.

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Note 1: The expression “acceptable risk” refers to the level at which further risk reduction will not result in significant reduction in risk; or additional expenditure will not result in significant advantages of increased safety.

Note: 2 The user and supplier may have different level(s) of acceptable risk.

Building packaging and processing machinery that meet the requirements of the ANSI/PMMI B155.1 standard will help manufacturers build a machine that is productive and achieves acceptable risk. Not meeting the requirements will leave the manufacturer open to product liability problems.

Other voluntary standards may also apply to packaging machinery such as NFPA 79 (electrical), ANSI B11.19 (safeguarding), ANSI Z535.4 (warnings) and ISO 20607 *Safety of machinery — Instruction handbook — General drafting principles*, ANSI Z244.1 (lockout/tagout) and others. ANSI standards are adopted and/or revised periodically, and the packaging and processing machinery manufacturer would be wise to stay current with ANSI's activities. A catalog of ANSI standards is available from ANSI on line at: <http://webstore.ansi.org/>

Complying With Government Standards

In the United States, all manufacturers must be aware of and consider the safety standards of the Occupational Safety and Health Administration (OSHA). While OSHA does not technically apply to manufacturers, it is a source that is frequently viewed by plaintiffs and their attorneys in trying to prove that a product has a defect. OSHA standards should be considered during the design process where applicable. OSHA standards are often outdated and ambiguous, thus they may not be very useful to the design engineer. OSHA publication 3067 *Concepts and Techniques of Machine Safeguarding* provides more specific guidance on OSHA requirements and it also refers to ANSI/PMMI B155.1 as a safety standard relevant for packaging machinery.

Government standards are promulgated by the Environmental Protection Agency (EPA), Food and Drug Administration (FDA) and other government agencies and should be used as applicable.

In the European Union, the primary government regulation that impacts packaging and processing machinery manufacturers is the Machinery Directive. The Machinery Safety Directive 2006/42/EC took effect December 31, 2009. The directive contains specific requirement for machinery manufacturers to perform a risk assessment of the product even if the product is built to an EN “C” level machine specific standards. Annex 1, section 1 of the new machinery directive states:

The manufacturer of machinery or his authorized representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

- *By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorized representative shall:*
- *determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,*
- *identify the hazards that can be generated by the machinery and the associated hazardous situations,*

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- *estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,*
- *evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,*
- *eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).*

The risk assessment requirement set forth in ANSI/PMMI B155.1-2016 follows the same iterative process detailed in the European Union Machinery Safety Directive 2006/42/EC and the “A” level EN/ISO 12100-2010 risk assessment machinery safety standard. The iterative risk assessment process is also defined in the ISO/IEC Guide 51. Harmonization of the ANSI/PMMI B155.1-2016 standard with EU directives and standards makes sense from a business and legal

defense prospective. Complying with the requirements of ANSI/PMMI B155.1-2016 will also comply with the EU Machinery Directive.

Making the Company Defendable

Making the company defendable involves improving the ability of the company to defend itself when litigation occurs.

One of the key elements in making the company defendable is to ensure that the packaging machinery complies with the applicable industry standards such as ANSI/PMMI B155.1. Non-compliance will present challenges to defending a claim.

Additionally, quality control measures (for component parts and the total product) are now widely accepted and, in many cases, standardized. Monitoring of product performance, including competitor information, has been formalized to a degree that trends can be identified and acted upon more quickly than in the past. As each of these functions mature, and as each are documented more meaningfully, manufacturers are able to use this substantive information to make changes to improve the products they sell and reduce or, in some cases, eliminate, product liability claims.

Product Liability Prevention In The Design And Manufacture Of Packaging and Processing Machines

The first place a manufacturer of packaging and processing machines should look in formulating product liability prevention (PLP) program is the design and manufacture of its own products. Within the context of product liability litigation, criticism will focus on what the manufacturer did, when it did it and what could have been done at the design and manufacture phases to have made a product with lower risk.

Thus, in U.S. courts of law, plaintiffs will often attempt to hold a manufacturer to a standard that requires the manufacturer to have foreseen almost every conceivable use and misuse of its product that could result in an injury. Although unwarranted, a company should expect this argument.

Research and Development

The manufacturer of packaging and processing machines must strive to achieve a design that is reasonably safe for its intended uses, reasonably foreseeable uses, and reasonably foreseeable misuses. The achievement of this goal is elusive, as criticism of a design will typically devolve to

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asking for the machine to be "safe," or with "zero risk" which is impossible to reach. Without doubt, in U.S. courts of law, a complainant will try to hold a manufacturer responsible to have "foreseen" almost every conceivable use and misuse of its product that resulted in an injury. These goals are obviously impossible and would result in a machine that cannot do its job. "Foreseeability" does not mean what can be conceived or imagined, rather, it is better defined as what is "objectively reasonable to expect." Through contact with customers, field service visits, and other means, the packaging and processing machine manufacturer must become familiar with how its machinery is used in the workplace and determine and analyze these reasonably foreseeable uses and misuses.

Analysis of the potential market for the product should include the abilities of the expected community of users of the product, how the product will be used, the environment to which the product will be subjected, the life expectancy of the product, and the frequency of repair and replacement of parts.

The Safest Machine

During a product liability trial, a plaintiff will frequently inquire as to whether or not the manufacturer employed tool(s) to produce the safest possible product. It is important to remember to keep these types of probes in proper context: that is, the machine design requirement is to achieve an acceptable level of risk. Otherwise stated, the manufacturer's obligation is not to build the "safest possible" machine, but rather one that is *reasonably* safe for its reasonably intended *uses* and *users*. Manufacturers will be questioned as to who within the company has taken the responsibility of applying safety engineering and human factors engineering principles to the product design. The best approach within a company is to use the risk assessment process, from the concept stage to the final manufactured product with the goal of reducing the risks associated the product to an acceptable level. There should be safety managers and/or engineers who have been designated to perform the risk assessment evaluations as a prominent part of their work. These individuals should be familiar with the risk assessment process as outlined in ANSI/PMMI B155.1-2016.

Quality Control

Quality control is an important part of product liability prevention because it can help defend claims of manufacturing defects. Several corporate practices can be implemented by the packaging and processing machinery manufacturer as a means of enhancing product safety and facilitating the defense effort should a claim occur. A system of quality control, testing and record keeping should be in place to promote effective claims management.

Maintaining an incident history with enough detail to determine how a machine was being used and/or misused at the time of the incident may assist the designer/manufacturer in determining whether or not there is any pattern of the actions which led to an incident and injury, and thus help to decide whether these actions are reasonably foreseeable uses and/or misuses that may need to be addressed with additional safeguarding, warning, instruction, or protective equipment. It is important to note that simply because some previously unforeseen misuse has occurred that has resulted in an incident, this does not mean that such misuse necessarily requires the manufacturer to respond with additional risk reduction measures. Although the new misuse has become reasonably foreseeable, the risks must be evaluated to determine if additional efforts are warranted by the manufacturer. In some cases, any additional risk

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reduction measures may be the machinery user's responsibility – such as locking out the machine, following procedures or warnings, etc.

The following items outline some of the actions that can assist a company in reducing its product liability exposure.

The packaging /processing machinery manufacturer's staff may need to engage in some of the following:

- Keeping current with industry standards and best practices.
- Set up a "product safety team" that is responsible for reaching the goal of acceptable risk for all machines.
- Review and evaluate injuries and complaints to determine if design changes need to be made or additional risk reduction needs to be added to machines.
- Collect and distribute applicable industry publications, ANSI/PMMI B155.1, relevant ANSI, ISO, EN reference standards etc.
- Maintain and update libraries.
- Attend safety seminars conducted by government, private industry and attorneys.
- Attend trade shows and conventions to monitor what competitors are doing with regard to product safety (state of the art).

- Coordinate activities with the engineering department and corporate risk management personnel.

1. Pre-Shipment Inspection Checklist

Develop a checklist to be used by assembly people when inspecting the machine prior to shipment. This is very important because this is the manufacturer's last contact with the machine before it leaves its hands.

- The reviewer should ensure that all risk reduction measures are in place, that warning signs are in place and that the manual and/or safety brochure is attached to the machine.
- The checklist should be dated and signed and refer to the machine by its model and serial numbers.
- A sample checklist is presented in Appendix A.

2. Photographs

Take photos of the machine just before it is crated (after the inspection noted above).

- Photos should be in color and show all guards and warning signs in place.
- Digital photos should be properly "backed-up" for permanent storage and accessibility.
- Put a small sign in the foreground of the photo in the digital image to identify the machine by its model and serial numbers and the date the photographs were taken.

3. Installation and Setup, on the Machine's Arrival at the Customer's Plant, by the Manufacturer's Employees or Authorized Representatives

- Complete an installation checklist during the installation. The content should be similar to the pre-shipping checklist.

- The checklist should be signed and dated and should identify the machine by its model and serial numbers.
- An installation report should be signed by the customer and the worker who will be working on the machine (if available). This report should attest to the fact that the customer understands all risk reduction measures of machine, that he/she has received

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a copy of the operator's manual and/or safety brochure, that he/she understands the basic operation of machine and that he/she knows never to operate the machine without the guards in place.

- Take photos before leaving as described, above, showing all guards and warnings in place.
- A policy should be developed and implemented that requires all employees and authorized distributors/service people to immediately orally report unsafe conditions or unsafe practices to the customer (to be followed by written notification). The same information should be reported to the manufacturer's safety department in writing. The manufacturer should then follow up with the customer. A sample letter is presented in Appendix B.

4. Service Calls

Complete a service report (see Appendix C) and take a photo of the machine after service is complete. The service report identifies the machine, is signed by the customer, etc. The report includes the following information:

- Guards and warning signs still in place?
- All safety systems, lockouts, etc. still operational?
- Operator's Manual still available?
- Is there a condition where additional safeguarding methods, warnings, and/or instructions need to be considered? If so, are there other machines in the field with the same condition that need to be evaluated?
- Instruct the repair technician to immediately orally inform the customer of unsafe conditions or unsafe practices and make this part of the technician's report to the machine manufacture home office. The manufacturer must follow up on all aspects of this report.

Machine (technical) file

The packaging or processing machinery manufacturer should set up a file for each machine according to serial number or other appropriate method to track the machine over multiple owners. What is in the file?

The technical file shall comprise the following:

- (a) a construction file including:
 - a general description of the machinery,
 - the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,
 - full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,
 - the documentation on risk assessment demonstrating the procedure followed, including:
 - a list of the essential health and safety requirements which apply to the machinery,
 - the description of the risk reduction measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,
 - the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

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- any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer,
 - a copy of the instructions for the machinery,
 - where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,
 - where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,
 - where appropriate a copy of the EC declaration of conformity;
- (b) The purchaser's purchase order and communications sent by the purchaser during purchase negotiations.
- (c) The manufacturer's invoice and communications sent by the manufacturer during purchase negotiations. Invoices should include:
- Model number.
 - Serial number.
 - Options purchased and not purchased.
 - Date purchased and date shipped.
 - Price.
 - Buyer's purchase order number.
 - Name of shipper or rigger.
- (d) Pre-shipment inspection checklist.
- (e) Pre-shipment photos.
- (f) Relevant engineering information such as bill of material, assembly and parts drawings, electrical drawing, PLC programs, risk assessment documentation, etc.
- (g) Copy of Owner's or Operator's Manual provided to purchaser (or evidence showing that the Manual was sent, when it was sent, and what version, i.e. date of Manual).
- (h) Post-installation checklist and photo. Reports of unsafe practices or conditions seen by the manufacturer's employees or reported by authorized representatives. These unsafe practices or conditions should be put into writing and given to the machine owner/user.
- (i) Receipts for registered mailings.
- (j) Reports of repair technicians and any other service people who visit the customer's premises during the years after the sale.
- (k) Documentation of spare parts orders and requests for service/repair and all other communications received from the customer after the sale.
- (l) Communications regarding new risk reduction measures, retrofits, unsafe practices, etc.

Miscellaneous

- Masters and engineering change requests
 - Maintain Master Copies of All Operator's Manuals, Safety and/or Sales Brochures, Advertisements, Product Catalogs, Warning Labels and Signs, Etc., and Every Revision Made to Them, with Records of the Dates of Such Revisions
- Continuing Product Development
 - Product development, changes in standards and technology may lead to product improvements which may be offered to existing customers. A record should be kept of these offers which provide additional risk reduction.

All such communications should be very carefully worded (so as not to jeopardize present or future lawsuits) and should be reviewed by the company's product liability

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attorneys. Communications of product safety improvements that are made available to the customer and are not necessary to make the machine reasonably safe, should never characterize the machine as being defective without the improvement. However, if the improvement will enhance the safety of the machine, make sure to communicate the benefits of the improvement to the customer. Make the implementation of the improvement attractive and as low cost in time and money as possible.

- Consider making any newly developed risk reduction measures that can be retrofitted onto existing machinery available “at cost” only (see Appendix D).
- Advertisement and Sales Brochures
 - Continually review and update to reflect changing designs, etc.
 - Advertisement and Sales Brochures Have product liability attorneys scrutinize before being used.
 - Limit any statements regarding safety, warranties, etc.
 - Store master copies as permanent records.
 - Complete records as to:
 - Where was advertisement published?
 - Written by whom?
 - How frequently published?
 - Identification of advertising agency
 - Dates of publications.

Warnings

Warnings play a very important role in product liability prevention because nearly every litigation case includes a failure to warn claim. Failure to warn claims occur because if a plaintiff cannot prove that a design or manufacturing defect exists with the packaging machine, they will argue that if only the manufacturer had told them about the hazard then they would have acted differently and avoided injury.

Warnings form an important part of machine safety. Warnings convey information about the existence and magnitude of hazards, and how users can avoid harm. Warnings are often applied on the packaging machinery and in the instruction manuals. There is some disagreement as to whether effective warnings actually reducing the risk of injury, but this is largely an academic controversy. Manufacturers need to warn machinery users of hazards associated with the use of the packaging or processing machinery. Failure to do so can create significant product liability problems. Additional information about warnings can be found in Appendix E.

Preparing and Organizing For a Product Liability Defense

If the company has prepared for and organized a product liability defense as part of the company's culture, managing the product liability claim will be easier than trying to do so when a lawsuit is served on the company. This section provides some recommendations on how to do just that.

Designate internal and external product liability coordinator(s); they will receive and respond promptly to all inquiries and/or claims. Limiting participation to a single person and a backup person in the event of the designated coordinator's absence saves both time and cost and

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eliminates the possibility of conflicting information being presented. It is of the utmost importance that the designated coordinator be thoroughly familiar with the entire product line and the methods by which it is manufactured. The coordinator should be able to communicate effectively to a diverse audience. Depending on the nature of the machine manufactured and the potential for, say, a catastrophic occurrence involving the machine, consider formal media training for the coordinator.

Inside the company, the coordinator should work with management and manufacturing to ensure that company policies relating to quality control, advertising, machine design, manufacturing methods and compliance with appropriate standards are followed. Of crucial importance is the preservation of vital records if a product liability lawsuit is filed.

It is almost always advisable to organize a *product safety committee* to assist and implement the work of the coordinator, as well as to implement any lessons learned from product liability activity. This learning process will help the company to improve the design and manufacture of its machines. The committee can be made up of people involved in the following functions: chief executive officer, legal, purchasing, quality control, insurance, sales and marketing, manufacturing and engineering.

On an external basis, the coordinator will serve as liaison between the company and legal counsel, providing the manufacturing information, technical background and qualified in-house experts necessary for a successful defense. Additionally, as the company representative, the coordinator will:

- identify the subject machine,
- provide preliminary determination of whether or not it is defective,
- respond to interrogatory questions,
- participate in any depositions and/or trial and
- actively take part in appropriate organizations and their working committees.

When a defense attorney is chosen, he or she should be experienced in dealing with product liability cases. Where possible, try to select counsel that is familiar with the product line or the packaging or processing machinery industry. The less time that needs to be spent educating the defense attorney with regard to the machine, its uses and misuses, testing, standards, warnings and so forth, the better. Having said that, it will always be necessary, no matter who is selected to defend the company, to make sure that counsel fully understands the company, its business, and its machinery.

Any outside expert hired to examine evidence and formulate opinions will require briefings, guidance and support from company personnel to ensure the latest information is known. The company engineering personnel should be deeply involved in this cooperative effort, all of which should be coordinated by defense counsel.

Establishing In-House Control

To avoid haphazard responses in a product liability case, such as recall, etc., it is wise to establish procedures that cover the following situations:

- Handling machine quality complaints.
- Reporting and processing product liability claims.
- Product recall.

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- Quality control inspection.
- Quality control non-conforming material action.
- Records retention.

Beyond the normal, everyday discipline expected in a well-organized manufacturing concern, many areas that are often forgotten or ignored can prove critical in product liability actions.

- Review and update warranties for accuracy.
- Review and update all advertising and catalog pages for factual accuracy; do not permit unsupported claims.
- Review and update all manuals, instructions, and similar materials, to make sure they appropriately advise of all potential hazards, how to use and maintain the machine safely, and how to avoid injury.
- Promote proper machine use in catalogs, in advertising, in manuals and on labels.
- Promote proper machine use through trade association activities.
- Purchase critical parts only from financially sound, high-quality manufacturers; identify the manufacturer for all critical parts and obtain insuring and indemnity agreements from parts suppliers.
- Keep aware of quality complaints; redesign as necessary.

Record Keeping

Keeping appropriate and important records can be critical to the defense of a product liability claim. Records generally of value in defending a product liability claim include:

- Design drawings
- Changes to designs, including the reasons for all design changes
- Documents showing the location on the machine of all safety devices, including guards, interlocks, emergency stops, and warnings
- Contracts, agreements, purchase orders, invoices, and all documents showing the terms and conditions of sale
- Correspondence with the purchaser or others involved in the sale
- Specifications, particularly specifications given by the purchaser
- Engineering drawings, including manufacturing/shop drawings
- Machine tests
- Shipping lists
- Owner's manuals, operating instructions, and similar documents
- Checklists verifying transmittal of all instruction manuals, operating instructions and similar documents, as well as verifying presence of all safety and warning placards, stickers and the like, and the presence of all guards and safety devices
- Photographs of the machine at the time of shipment or sale
- Installation reports
- Subsequent correspondence with the purchaser concerning the machine

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- Repair/Service reports
- Standards related to the machine line; for example, American National Standards Institute, federal and military, ISO
- Vendor insurance agreement.
- Educational material published by the trade association or company
- Catalogs
- Company warranties
- Machine technical construction file as required by European standards

Although this is not a complete A–Z list of exactly which records to keep, most of the important ones are included. Remember to scrutinize all the things written and filed, then ask what value a plaintiff's attorney might place on today's information as tomorrow's evidence. As important as it is to keep critical records, it is equally important not to create damaging records or “smoking guns.” This is not to say that the company should ever fail to document matters that should be documented simply because of a fear that those documents might later turn up in a product liability suit. The key is to simply exercise appropriate prudence, caution and control when creating documents that report matters that might adversely affect the company in a product liability suit. A few basic rules, if followed, can potentially prevent bad documents from being created:

- Assume that anything written may later be shown to a jury in a product liability suit; can the message be communicated in a better, clearer way?
- Avoid using the words “defect” or “defective” when referring to the design, manufacture, or warnings associated with a machine.
- Avoid pointing blame and avoid unnecessary adjectives and pejoratives (e.g. “The engineering team made a huge mistake when it failed to include a guard for the in-running nip point on the machine and that decision is going to cost us millions the next time someone gets hurt.”)
- Don't be afraid to record potential problems with a machine or its design when attempting to improve the machine. However, all documents which identify potential problems must be followed with a document that shows what the company did to investigate the potential problem and how the matter was resolved. **CLOSE THE LOOP.**
- When in doubt, consult an attorney. Particularly if the company must respond to a complaint by a purchaser or where the company needs to identify and address a potential design or manufacturing defect, it should consult an attorney before anything is committed to writing.

Finally, the company should have a formal records retention and destruction policy and should assure that it is strictly enforced. However, as noted, above, all such policies must be suspended relative to documents pertinent to a machine involved in a lawsuit as soon as the company is notified of the claim.

Post-Sale Duties and Obligations

Manufacturing a packaging machine includes identifying hazards associated with the use of the machine that were unknown or undiscovered at the time of manufacture. When such a hazard is identified, the manufacturer's potential post-sale duties may become relevant.

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Perhaps no area of product liability law is more unsettled than the area dealing with the obligations of a manufacturer after it sells its machine. Potential post-sale obligations generally fall into two categories: recalls/retrofits, and post-sale warnings. Volume 2 of this *Guide* delves in to the post sale duties for legacy machinery in greater detail.

Implementing Product Recalls

Whether and to what extent a manufacturer has a duty to recall or retrofit a machine after sale is largely dependent upon federal regulations and state law, and different states have different views on the duty to recall or retrofit.

It is probably fair to say that at the current time, most states generally do not impose a duty to recall a machine on a manufacturer of a machine or piece of machinery after it has been sold. This is certainly truer where the machine in question was not defective at the time of manufacture, but, through new technology, may now be made to be less hazardous. However, if a manufacturer learns after it has sold a machine that the machine was dangerous or defective at the time of sale, there may be more cause for concern and there may exist a duty to recall or retrofit the machine with upgraded safety devices. Simply by way of example, Georgia law provides that when a manufacturer subsequently learns that its machine has been sold with dangerous defects, it is under a duty to recall the machine from the market and to remedy the defect or replace the machine in some cases in the exercise of ordinary care beyond the duty to give a post-sale warning.

Thus, when a manufacturer receives notice or knowledge that a machine it sold contains a defect, it must perform an analysis of whether the defect or hazard requires some type of affirmative corrective action, such as providing a retrofit, recalling the machine entirely or issuing some type of warning to apprise users of the potential risk. In other cases, a duty to recall may be statutorily imposed, which could expose the manufacturer to civil and/or criminal penalties if the recall is not undertaken.

There are recalls that are mandated by statutes such as the Consumer Product Safety Act, the National Highway Traffic and Safety Act and the Food, Drug and Cosmetics Act. These statutes empower the particular federal agency to order a recall and typically provide that manufacturers must inform the agency if they become aware that their product contains a defect that would create a hazard to the public. But because these statutes would not appear, on their face, to deal with packaging and processing machines, the manufacturer of packaging and processing

machines is often faced with a difficult decision in cases where there is not a statutorily mandated recall and the decision on whether to recall the machine must be made by the manufacturer itself.

Post-Sale Warning and Retrofit/Recall Obligation

Most courts recognize that a manufacturer is in the best position to either discover or learn of dangerous machine defects and to determine how to correct such defects through remediation. The manufacturer has superior knowledge of potential hazards and the ability to find them, because notice of the defects comes to the manufacturer through product testing, quality control, product complaints, product liability suits, warranty suits, government-imposed recalls, and industry experience. As a result, particularly in the case of consumer products, most states do maintain that a manufacturer may be obligated to provide post-sale warnings of machine hazards or defects under certain circumstances and in accord with various federal consumer protection codes and regulations.

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Where a knowable, dangerous defect exists in the machine at the time of distribution that could have been discovered and was within the state of the art at the time of distribution but did not become known to the manufacturer until a later time, a jury is likely to find that the manufacturer must issue, at a minimum, a post-sale warning. Failure to do so could result in the award of compensatory and even punitive damages against the manufacturer. An illustrative case is *Gilham v. Admiral Corp.*, 523 F.2d 102 (6th Cir. 1975), Cert. denied, 424 U.S. 913 (1976). In *Gilham*, the plaintiff sustained burn injuries as the result of a fire caused by her Admiral 24A2 television. The plaintiff contended that the fire was caused by the television's high-voltage transformer in that some of the insulation components therein could not withstand the heat generated by the transformer. Prior to the plaintiff's fire, Admiral had become aware that the transformer operated at a higher temperature than anticipated, such that the risk of a 24A2 catching fire became reasonably foreseeable. In addition, Admiral had received several reports of fires in its 24A2 model prior to plaintiff's fire and had conducted tests which confirmed that the transformer was the origin of the fires. Nevertheless, Admiral failed to warn existing owners of the 24A2 sets of these hazards and continued to market the television without redesigning it. The Sixth Circuit reversed the lower court and reinstated the jury's assessment of punitive damages against Admiral:

We conclude that the evidence ... was sufficient to permit a reasonable person to conclude that Admiral knew that its design posed a grave danger to the lives and property of its customers, and therefore that its failure to redesign the set or warn the public was conduct sufficiently intentional, reckless, wanton, willful or gross to permit a reasonable inference of malice. 523 F.2d at 109.

Situations can also arise where there is a change in the state of the art, such as the development of a more effective safety device or an improved design, which may trigger post-sale obligations. Generally, the manufacturer is under no duty to notify customers of changes in the state of the art pertaining to the safety of the machine if the machine complied with the state of the art at the time of sale. Courts have held, however, that a jury may determine that such a duty exists, depending on the nature of the industry, the warnings given originally, the nature and intended life of the machine, the nature of the safety improvements, the number of units sold, marketing practices and consumer expectations.

For example, in *Kozlowski v. John E. Smith's Sons Co.*, 87 Wis.2d 882, 275 N.W.2d 915 (1979), a sausage stuffing machine manufactured circa 1938 was involved in an incident in which the plaintiff's decedent was killed. A bypass valve, which first became available for the machine as an option in 1946 and as standard equipment in 1971, would have prevented the incident. The

Wisconsin Supreme Court reversed the directed verdict entered in favor of defendant Smith's, holding that the existence of a post-sale duty to warn of the existence of the bypass valve was a jury question. The court explained:

We do not in this decision hold that there is an absolute continuing duty, year after year, for all manufacturers to warn of a new safety device that eliminates potential hazards. A sausage stuffer and the nature of that industry bears no similarity to the realities of manufacturing and marketing household goods such as fans, snowblowers or lawn mowers, which have become increasingly hazard proof with each succeeding model. It is beyond reason and good judgment to hold a manufacturer responsible for a duty of annually warning of safety hazards on household items, mass produced and used in every American home, when the machine is thirty to thirty-five years old and outdated by some twenty newer models equipped with every imaginable safety innovation known in the state of the art. It would place an unreasonable duty upon these manufacturers if they were required to trace the ownership of each unit sold and warn annually of new safety improvements over a thirty-

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five year period. As noted, the sausage stuffer machine industry is far more limited in scope. Consequently, a jury in determining a manufacturer's duty in this restricted area must look to the nature of the industry, warnings given, the intended life of the machine, safety improvements, the number of units sold and reasonable marketing practices, combined with the consumer expectations inherent therein. 275 N.W.2d915,923-24. Where the machine has defects at the time of sale, the manufacturer that subsequently discovers those defects can avoid or mitigate future liability by taking reasonable corrective measures. See, e.g., *Braniff Airways Inc. v. Curtiss-Wright Corp.*, 411F.2d451 (2d Cir.), Cert. denied, 396 U.S. 959 (1969) ("It is clear that after such a product has been sold and dangerous defects in design have come to the manufacturer's attention, the manufacturer has a duty either to remedy these or, if complete remedy is not feasible, at least to give users adequate warnings and instructions concerning methods for minimizing the danger"); *Balido v. Improved Mach. Inc.*, 29 Cal. App.3d 633, 105 Cal. Rptr.890 (1972).

Managing the Product Recall

Once the decision to recall the machine has been made, the manufacturer must determine what steps should be taken to carry out the most effective and efficient recall campaign possible under the circumstances. The level of advanced planning and preparation will vary depending on the packaging machinery, the manufacturer's history with the machinery, and the number of machines manufactured – one, ten, hundreds, thousands, etc.

A manufacturer's best chance to avoid future liability arising out of the recall includes the following: offering a free-of-charge recall; timely and adequately communicating that offer; warning owners and users of the machine of the risks and hazards of using the machine during the period before the recall is completed; and employing reasonable follow-up procedures to ensure that the recall is successful.

In this regard, there are at least five basic areas that must be addressed by a company undertaking a recall:

1. planning the mechanics and logistics of the recall,
2. implementing the recall,
3. evaluating and monitoring the recall,
4. taking follow-up action if necessary and
5. terminating the recall program.

Product recalls have been performed in different industries with varying degrees of success. The methods and means to achieve a successful recall continually evolve based on lessons learned.

In the unlikely event that a recall of a packaging machine may be warranted, the manufacturer should seek the most current methods to achieve success in the above five recall areas.

Conclusion

The potential post-sale duties of a machinery manufacturer involve fairly complex legal issues and can require a large commitment of company resources in terms of both manpower and funding. The changing nature of potential post-sale product liability duties, however, suggests that today's prudent manufacturer to respond appropriately to ensure that risks attendant to the use of its machine are reduced to an acceptable level and that the company's decisions in that regard are defensible.

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What to Do When Litigation Is Unavoidable

As a packaging or processing machinery manufacturer, make every effort to produce machines that achieve acceptable risk and are useful to the consumer. Nevertheless, on occasion, the company may be faced with a lawsuit regarding a machine.

This section of the *Product Liability Prevention Guide* provides general guidelines for corporate manufacturing defendants involved in litigation. It is not intended, nor should it be construed, as legal advice. Rather it is meant to act as a general guide for dealing with today's litigious environment. For specific advice, there is no substitute for having product liability counsel. This is especially true because of the differing rules among various jurisdictions that affect many important areas that establish, mitigate or, in some cases, negate liability for an event.

In this section we suggest some steps to take when the possibility of a liability claim first arises.

Collecting Information on the Occurrence and the Machine

Notice of an Incident

Notice of any incident involving a company machine should be taken very seriously and handled appropriately. Any injury could become the basis for a product liability lawsuit so notice of an injury should be treated very seriously.

Notice of an injury can come from any one of several sources. The customer may call requesting assistance with the incident or about information inquiring about guarding updates. The injured party may contact the company. Newspaper reports or third parties may bring the incident to the attention of the company. The least desirable notice but one that does happen occurs with the receipt of a legal Complaint notifying the company of a product liability lawsuit.

When the company first suspects a possible product liability claim resulting from packaging or processing machinery it manufactured, act promptly to start a case file. Listen carefully to determine the extent of the problem. Collect as much information as possible on any injuries or damage, the names of anyone involved and when, where and why the incident happened. Take careful notes and then sign and date the notes. It is important that the information be factual in nature – do not assume, speculate or engage in hypotheticals. This is often ignored and, unfortunately, can often create issues in a later lawsuit that are not supported in the facts, but become an issue because the specter arises in investigative materials. The form shown in Appendix F can be used to record the initial information but is not required. Reproduce the form or modify it to better suit the company's needs. Additionally, immediately consult counsel for aid and advice in conducting any investigation of the claim as outlined above, including interviewing witnesses and the like, so as to cloak these communications in the Attorney-Client Privilege as and where appropriate.

Do's and Don'ts to Help the Defense

- Do be courteous, pleasant and cautious. A harsh response or indifferent attitude could actually cause a lawsuit by antagonizing the injured party. Even if the person is certain to sue the company, treat them with respect and courtesy.
- Don't provide information or opinions on the machine unless and until the company lawyers have been consulted.
- Don't admit the machine or part is the company's until it is absolutely known for certain. Even if identifying information is provided to show the machine is the company's, you will not know if there has been a material alteration until the machine can be examined.

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- Collect information. Do not volunteer information that is not requested; the goal is to collect information.
- If possible, have any calls or correspondence that may be related to a liability situation handled by one person.
- **BE FACTUAL!** This is not the time to offer opinions on what might have happened to cause an incident. Record what is needed to evaluate the incident so that, after all facts are gathered, a careful investigation can lead to solid conclusions. Do not make assumptions or judgments about suspicions – no matter how strong the urge is to do so. Realize that as the claim proceeds, any person will likely be called upon to defend anything said or written at this point – defending facts is preferable to trying to defend snap judgments.
- In the same manner, do not make statements that jump to conclusions or that air dirty laundry – collect information, offer assistance when and where needed, but avoid opinions and frustrated comments.
- Notify the company's legal counsel and insurance agent or broker as soon as possible.
- Make sure to notify the insurance carrier of every actual or potential lawsuit immediately upon receipt of a claim.
- Unless you're a lawyer, don't talk about the law.
- Work as a team with the attorneys, insurance company, agent, dealer and/or distributor.
- If the machinery is returned to the company, do not let the machine or part that is involved in an incident get out of its hands. Consult with your attorneys before agreeing to take custody of any machine involved in an injury or other claim. Many states recognize a claim for spoliation of evidence. Tag components or parts with the date on which they were received and keep them safely in custody. From past experience, legal cases a packaging machinery manufacturer normally could have won were lost because a part was discarded or lost and unavailable to the defense attorney during litigation. It is often preferable for a third-party to maintain custody of the allegedly defective machine or part.
- Make a note of any apparent changes, modifications, or alterations to the machine from its original condition. Document same photographically.
- **BE SELECTIVE OF WHO IS INVOLVED:** Make sure the representatives know the machine and know what to do and not do in litigation matters. Persons involved in the incident investigation or assisting in the defense may be deposed during the litigation. If persons are not well suited to testifying, do not include them in the investigation. Again, having experienced defense counsel direct these efforts will avoid missteps that may impede the manufacturer's defense in any later lawsuit.

- Avoid negative comments such as:
 - I was afraid something like that would happen one of these days...
 - I know it doesn't seem (look) as well built...
 - We've had quite a few customers with the same problem...
 - I've wondered when somebody would have trouble with...
- Always say (assuming it's true):
 - We'll do everything we can to help with this issue.
 - How did this happen?

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- How was the machine being used at the time of the incident?
 - Were the directions or instructions on the machine or in the manual followed or known?
 - We want to get all the facts so we can assist.
 - Please tell us everything that happened and anything that might be important.
- In litigation, the injured party, or plaintiff's, counsel often will seek information concerning prior claims or lawsuits. Under certain circumstances, the company may need to provide that type of information to plaintiff. Therefore, it is recommended that the company keep a list of all claims and lawsuits, identifying the name of the claimant/plaintiff, the date of injury, the machine in question, a detailed description of how the incident occurred, the alleged defect or hazard, the court where the suit was filed (if one was filed), and the outcome of the claim or action.
 - For important depositions (e.g. plaintiff's deposition, plaintiff's expert's deposition), consider having the in-house machine specialist present to assist defense counsel at the deposition.
 - For all company depositions, make sure to allot sufficient time to meet with defense counsel to properly prepare for the deposition. If a company witness has never been deposed before, consider having the defense counsel conduct a mock deposition of the witness. *Do not* wait until the day of the deposition for these activities. Preparation activities should take place several days prior to the deposition, with time allotted for a brief refresher on the day of the deposition.
 - Request that the defense counsel provide periodic (e.g. quarterly) status updates on the litigation. Review such updates carefully and be sure to stay abreast of any important developments with the company's lawsuit.
 - All safety features required to prevent end-user exposure to hazards should be in place. (When in question, applicable ANSI, NFPA, NEC and OSHA standards and codes, as well as any other applicable industry standards, should be consulted).
 - Be familiar with and follow ANSI/PMMI B155.1, *Safety Requirements for Packaging and Processing Machinery*. Risk assessment is a critical factor in successfully reducing risks to an acceptable level. Hazard identification and risk assessment enables engineers to identify possible hazards and to choose alternative designs or solutions to eliminate, mitigate, or control the risks. All potential hazards should be eliminated, appropriately guarded or enclosed. Hazards include moving parts, transmission components, and points of operation, blades, heat sources, electrical hazards and chemical exposures.
 - All machinery should be supplied with detailed written safety precautions and instructions for use, as well as instructions for troubleshooting, maintenance, repair, lock-out/tag-out and so forth. These manuals should be reviewed and updated frequently.
 - Warning labels should be permanently affixed at hazard points.
 - Any written instructions, guarantees, or warranties should receive legal review to ensure that the wording is appropriate and does not imply unintended guarantees or warranties or inappropriate safety promises.
 - A formal quality control program should be in place to ensure manufacture of a high-quality machine. Such a program should include inspections for quality, performance and safety.
 - If subcontractors are used, they should be required to carry insurance, to add your company as an additional insured on their insurance policies, and to furnish the company with copies of the policies and certificates of insurance as proof that they have

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added the company as additional insureds on their policies. Limits of insurance should be greater than or equal to those of the packaging machinery manufacturer. The manufacturer should verify that the subcontractors' insurance carriers are acceptable. (Note: if subcontractors do not carry adequate limits of insurance with acceptable insurance carriers, if a loss ensues then the manufacturer's insurance will respond. This can then affect the amount of the manufacturer's general liability premium.) Place the subcontractors and their insurance carriers on notice of all claims, and demand that they provide the company with a defense and indemnification against any loss occasioned by any defect in the component parts and/or services provided that are the subject of the suit or claim.

Create an Incident File on The Machine

In order to assist in the defense of a potential claim, an incident file is helpful for the entire defense team. Collect the available information about the occurrence and gather information about the specific machine involved in the incident.

At a minimum, this file should include all correspondence, contracts, agreements, purchase orders, manuals, all photographs, and all other documents relating to the particular machine in question. At a point, the engineering drawings and documents concerning the design and manufacture of the machine will also be necessary and helpful. Many times, these items are not as readily available or too voluminous to keep with the incident file. If it is possible that more than one person might have documents that should be in the file (e.g. emails or other such documents), be sure to obtain those documents from those persons.

Clearly identify or label the file and keep the file in an area where it will not be destroyed or lost. Make sure that it is flagged so that nothing will be removed or purged from the file pursuant to the company's normal document retention/destruction policy. It is important to remember that electronically stored information and communications (ESI) is now discoverable in all jurisdictions and certain duties may exist to preserve and protect ESI from destruction, even if done pursuant to normal company guidelines for the purging and maintenance of its servers and databases. The handling of ESI should be discussed with counsel and/or appropriate electronic discovery consultants to better understand the principles and requirements involved. Regardless, notice of a claim or lawsuit virtually always triggers the need for implementation of a Litigation Hold and suspension of normal document destruction policies over all documents associated with the machine and its design, manufacture and sale.

In many instances, it may be possible to gain possession of the machine or critical component parts. Remember that steps must be taken to preserve and protect the machine and/or parts. Do not alter or dispose of them unless and until all parties with an interest in the evidence are notified and consent. Recall that failing to follow this approach may subject the company to spoliation of evidence claims, which may provide legitimacy to otherwise questionable claims.

A successful defense of a product liability lawsuit involves the active participation of company personnel, particularly the company's product liability specialist or liaison. By following some or all of the steps set forth below, the company can significantly contribute to the successful defense of any product liability lawsuit. This list applies to all companies, including those who are self-insured, those with large deductibles and those who are totally insured with no deductible. Even if the company has insurance coverage, realize that the company is the defendant in the case, and it has not only a right but a duty to make sure the case is prepared properly. In addition,

even if the company is insured, the insurance rates vary in accordance with the company incident experience. Thus, it is necessary to become involved in all cases where there may be insurance against any financial losses, not just those in which there is financial involvement by the corporation manufacturing the machine.

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- Be involved in the selection of defense counsel. Secure an attorney who routinely handles product liability cases and, if possible, someone who is familiar with the packaging machinery industry or who has defended other large industrial machinery.
- Educate the defense counsel concerning the specific machine in question and the company, including the design process and risk assessment or similar analyses performed by the company in connection with the design process. This education process should be done, if at all possible, in a face-to-face meeting at the company's plant or offices.
- Make copies of the entire machine file and/or technical construction file and provide those documents to defense counsel as soon as possible. Be available to answer all questions that the attorney might have concerning the documentation.
- Arrange for an inspection of the machine as soon as possible, and make sure that a company representative who is very familiar with the product or machine in question is included in the initial inspection of the machine. Confirm that the machine in question is indeed one of the company's machines. Note all machine identification numbers and information. Note whether any changes or alterations or modifications appear to have been made to the machine. Document the inspection via photographs and/or video. Be sure defense counsel is involved in directing this process, and strongly consider retention of an outside engineering consultant to participate. Such consultants will typically have greater familiarity with the litigation process than your in-house engineer and may recognize or appreciate items in the inspection that might go unnoticed by the company engineer.
- Make sure that proper attention is accorded to reviewing and responding to interrogatories and document requests directed to the company. The interrogatory responses must be verified under oath by a company representative and, therefore, those responses can be used against the company later in depositions and at trial. The information provided must be accurate and complete. If the company has been involved in other litigation involving the machine, review past discovery responses to assure consistency or update the information conveyed if necessary. Likewise, it is important that proper attention is given to gathering all documents called for by the document requests, including those stored electronically, such as e-mails. If a company fails to produce all of the requested documents, the court can and will order monetary sanctions against the company, and may even award a "default judgment" against the company, in essence ruling in favor of the plaintiff without requiring proof of machine defect and awarding the plaintiff his or her damages.
- Keep a "Litigation File" that contains all prior interrogatory responses made by the company in other lawsuits. It is very important that the company's responses remain consistent (where appropriate) from suit to suit, so that plaintiff's counsel is not able to utilize discrepancies to the company's disadvantage.
- Utilize a form such as the one provided in Appendix F to document the findings and activities related to the litigation, taking care to confine its use and dissemination to only management and those directly involved in the handling of the litigation.

Notifying the Carrier and Agent

Since there are many ways in which the company may become aware of an actual or potential product liability claim, the times at which it should contact its independent insurance agent and

the insurance company may vary. The company specific insurance policy will likely contain reporting requirements that should be familiar to the incident coordinator. Do not assume that

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a large self-insured retention or deductible automatically relieves the company of reporting a claim. **READ THE POLICY!**

In all severe injury incidents, the company should notify its carrier and agent as soon as possible. These include when the company is served with a lawsuit or when a demand is received indicating a claim is likely. Other times, however, the decision of whether or not to report a claim to the carrier is left to the company's discretion. The company's insurance agent or broker should always be notified of incidents or potential claims and should guide the company on reporting issues to the carrier. Reports of minor injury or property damage may not turn into significant, or any, claim. Again, working in conjunction with defense counsel, risk department and claims professional will guide the company's decisions in this regard. Remember, **READ THE POLICY** to make sure the company does not compromise its insurance coverage.

Given the intricacies of insurance law, in cases where the potential exposure is significant, it is often advisable to engage counsel to assist in the investigation and in the dealings with the carrier in order to preserve the company's rights. If the company does engage counsel, keep them advised of the investigation and activities.

Coordinating With the Carrier And Counsel

Once a suit has been filed, it will be the responsibility of the company and its defense counsel to fully investigate the claim.

After the insurance carrier has been notified of the product liability claim, it and defense counsel will need assistance in properly defending the claim. Since the company knows its machine's engineering and design, safety features, proper uses, common abuses, advertising, quality controls and the like, the logical place for counsel to get assistance is from the company. The best defense usually comes from the company's knowledge of its machines and of the company itself. If possible, choose a liaison within the company that can speak from experience concerning the machine. At the least, if the person with good technical knowledge cannot be the liaison, provide a contact who is able to get the necessary information with ease. The liaison should be able to do the following:

- Coordinate the exchange of information, both investigative and substantive, between the company, counsel and, if applicable, the insurance company;
- Arrange meetings between defense counsel and critical in-house witnesses/experts;
- Arranging meetings to answer interrogatories properly;
- Keeping relevant departments in the company abreast of developments;
- Suggesting to defense counsel what expert witnesses (or at least type of witness) the company might want to use;
- Managing all correspondence with the defense counsel.

Smooth, accurate and effective communication between the company and its defense team is a critical factor in presenting the best possible defense. Make certain that all involved team members work with the latest case information available. Last-minute surprises are counter-productive and can be embarrassing to the defense team. Remember that the defense team realizes the distraction and challenges of defending a product liability claim – but they are working in the company's best interest to minimize its exposure.

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Defending the Product Liability Lawsuit

The successful defense of a product liability lawsuit demands active, committed participation by the company and strong teamwork between the insurance carrier and defense counsel. The company should be involved at every stage of the claim, and the groundwork should be laid even before any claim is received. Everyone benefits when the company commits knowledgeable people with authority to act on its behalf. Below are some particularly important points to follow.

Initial Assessment of the Claim

The following provides a guide to the types of steps likely to be taken in connection with the initial assessment of the claim asserted against the company.

Defense counsel will want to obtain the entire Machine Technical File concerning the machine in question and will need to become fully educated on all aspects of the machine and its proper operation. This will require that the company task a technical professional to assist defense counsel in this regard, preferably someone who could also sit for a deposition in the case if needed.

Defense counsel will need to learn everything that the company knows about the claim and incident in question; any records that have been created by the company after it was first notified of the claim should be produced to counsel for his or her review. Counsel will instruct the company as to the privileged nature of documents prepared by the company in anticipation of a lawsuit, and the company's employees should be instructed that they are not to discuss the case with anyone other than management and defense counsel.

Defense counsel will attempt to arrange for an inspection of the machine in question. A company representative with knowledge of the machine, its design and its function, and its condition at the time it left the company *must* attend the inspection. At the inspection, photographs and videotape will be taken to preserve a record of the machine in question and to show the machine in operation. Among other things, counsel will be looking for any evidence that the machine has been altered after leaving the facility, a potential defense to the product liability claim.

Defense counsel, in consultation with the company and the insurance carrier, may want to engage an outside expert early in the process who can assist with the defense and who may be later called upon to testify at trial to render opinions concerning the machine and cause of the incident.

Once defense counsel has completed these initial steps, he/she will prepare a formal, written response to the allegations of the plaintiff's complaint. The complaint is the formal legal document filed by the injured person that initiates the lawsuit. The company must respond in writing to the allegations set forth in the complaint.

The Discovery Process

The discovery process in a product liability lawsuit involves the exchange of information between the plaintiff(s) and defendant(s). Because the parties are adversaries, the exchange does not always progress smoothly.

Written Fact Discovery: Interrogatories and Document Requests

The discovery process of the lawsuit allows each side to the dispute to "discover" facts and information possessed by the other side. Discovery takes different forms, including written discovery, in which the parties are permitted to serve upon each other written interrogatories, or

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questions, which must be answered under oath within a certain time-period, usually about thirty (30) days.

This discovery phase also allows the parties to serve each other with written document requests, pursuant to which the responding party is required to produce copies of requested documents relating to the allegations of the lawsuit and other relevant matters. As with interrogatories, document requests must be responded to within a certain time-period, usually about thirty (30) days. Items requested may include machine drawings, specifications, testing, warnings, catalogs, advertising, instructions, process specifications, quality control procedures, warranties, etc., and may include requests for not just written materials, but also electronically stored documents such as e-mails and the like.

Immediately upon receipt of a claim, all company staff must be notified that any documents potentially relevant to the case must be retained and to suspend any scheduled document destruction programs or procedures for the duration of the lawsuit.

If interrogatories and/or document requests are served upon the company, defense counsel will need to work with a designated company representative to respond to the questions set forth in the interrogatories and to gather the documents requested by the document requests.

Defense counsel will also submit interrogatories and document requests to the plaintiff, usually to learn the identity of any witnesses to the incident, the nature and extent of the plaintiff's injuries, the names and addresses of all treating doctors and hospitals, and the amount of claimed damages. Counsel may require the assistance of the company's technical personnel to help frame appropriate questions about the operation of the machine and so on.

Oral Fact Discovery: Depositions

The other form discovery typically takes is oral discovery, or depositions. After the parties have received and evaluated responses to any interrogatories and/or document requests served, depositions will be taken. In a deposition, the attorneys are given the opportunity to ask questions of witnesses, who are placed under oath, and the questions and answers are transcribed by a court reporter for later use in court.

The lawyer for the plaintiff will notify defense counsel of those company representatives who are to be deposed. Typically, these are individuals disclosed in the answers to the written discovery who have had involvement in the design, manufacture, sales and marketing of the machine. Defense counsel will then meet with all company witnesses before their depositions to prepare them to be deposed. The purpose of the preparation session is to advise the witness of the deposition process and what to expect in that regard, to review what information the witness has concerning the machine or other aspects of the claim, and to review any pertinent information so that the witness is prepared to testify knowledgeably and truthfully to all questions likely to be asked at the deposition. A company witness should be prepared to meet with defense counsel for several hours on a day prior to the deposition, and to then spend up to several hours being deposed.

Defense counsel will depose the plaintiff and witnesses to the incident, to fully understand and document the incident, the possible causes, and to begin to develop the facts that will form the basis of the defense to the lawsuit.

Expert Discovery: Expert Witnesses

Most product liability suits involve expert witnesses. Indeed, in some states, the plaintiff, or injured party, may not proceed with a lawsuit without one. The plaintiff will engage an expert

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witness (i.e., a mechanical engineer) to offer opinions concerning the design of the machine (i.e. that the design was defective because it failed to properly guard a hazard, or that a manufacturing defect caused the injury). The company may also engage an expert witness to rebut the plaintiff's expert's opinions. It is important for the company to be involved in the

identification and selection of the defense expert witness. The company may know of or be familiar with persons whose qualifications and credentials will make them a strong and credible expert witness. Likewise, company personnel may have useful knowledge of the plaintiff's expert.

If the plaintiff's expert witness prepares a written report, appropriate company personnel will be asked by defense counsel to review the report and discuss the report (including all weaknesses, misstatements, etc.) in preparation for the deposition of the expert which will be taken by defense counsel.

Settlement

Typically, at some time before or during the company's day in court, the subject of settlement will arise. This is a crucial decision and will require a studied judgment based upon opinions by defense counsel, corporate counsel, the claims representative and engineering personnel. Although the insurance carrier generally has the discretion to decide whether or not to settle a case, it will usually consult with the company first. This will usually involve a balancing between defense counsel's views on the likelihood of success at trial against the exposure presented by the likely verdict value of the case should the jury find for the plaintiff, the venue for the lawsuit, the judge, and the costs of proceeding with a trial. Often, these costs are measured not just in terms of the legal fees and the like, but also in terms of the time company personnel will need to devote to attending the trial and so on.

If the company feels it has organized a strong defense, conscientiously produced a quality machine which has been proven to the company's own satisfaction to safely function as it was intended to, and the company either cannot or does not want to settle the claim, it should be prepared to defend the case through trial. Remember, juries are composed of ordinary citizens who will generally treat organizations fairly, especially if during the screening process, the prospective jurors are asked individually if they can rule as favorably for a large company as they could for an individual.

The company may decide that the cost associated with litigation, together with the risk associated with a possible unfavorable verdict, do not justify taking the case to trial. This is particularly true if the investigation of the claim and review of depositions and other materials produced in the discovery stage of the lawsuit indicate that some aspect of the design, manufacture, or warning of the machine may have contributed to the incident.

Trial

If the case goes to trial, the defense team will work with the company's personnel to ensure that they are well prepared to participate in the trial. Thorough preparation is **the** critical element of success.

Company employees who are likely to testify at trial will be prepared in advance to enable them to testify as thoroughly, knowledgeably and truthfully as possible. Even company employees who are not expected to testify may be asked to stay in contact during the course of the trial to assist defense counsel by answering technical questions or providing clarification of a particular concern.

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Manufacturers of packaging and processing machines should avoid the trap used by plaintiffs that the ANSI/PMMI B155.1 safety standard is a "minimum standard," inferring that a machine that meets this standard is only "minimally" safe. The ANSI/PMMI B155.1 standard has been developed over a period of decades by individuals with expertise in the safety of packaging machinery who come from many disciplines with literally hundreds of years of combined experience in applying safety to packaging and processing machinery. While the legal community may claim that meeting the standard is a necessary, but not sufficient condition for

a reasonably safe design, manufacturers of packaging or processing machines who apply the safety standard to their design are doing so to achieve what is considered to be a reasonable level of safety in their designs. The specifics of how a particular manufacturer met the requirements of the ANSI/PMMI B155.1 safety standard will most likely be in dispute in a legal matter. This *PLP Guide* will help a manufacturer/designer in meeting the safety requirements set forth in the standard in a manner so as to produce a packaging or processing machine with risks reduced to an acceptable level.

Conclusion

Product liability litigation can present the manufacturer with enormous risk. The uncertainty of the jury system, not to mention the potential costs in terms of financial and other resources, and the potential damage to the company's reputation and prestige, make every product liability suit something to be taken very seriously. If the company has followed the steps outlined, above, it will be well on its way to a successful defense. The benefits of a successful defense may include reduced insurance costs and an enhancement of the reputation and integrity of the packaging and processing machine and the company itself.

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INSURANCE COVERAGE Q & A

This *Guide* has briefly discussed how to prevent product liability lawsuits and what to do in case of a lawsuit. Understanding how to build a safe machine and how to improve the company's ability to defend itself are important aspects of product liability prevention. Understanding the legal process for litigation often raises questions about product liability insurance coverage.

The following information is intended to be a basis for discussions with a risk management advisor or insurance broker/agent. The company may choose to ask the questions as they are stated, reword them to fit its needs and current knowledge level, or develop its own questions and discussion points.

Q. How much insurance is adequate? Do I need umbrella coverage?

A. Most commercial general liability policies offer a limit of \$1 million per occurrence and then an aggregate limit that represents the total number of occurrences (assuming all limits are exhausted) within a policy period. An umbrella policy will offer additional limits in increments of \$1 million. The limits to be purchased can be determined by the size of the asset base of a company and that of its owners. A popular gauge is estimated revenues on an annual basis. A rule of thumb for adequate coverage is an umbrella limit of 30%–50% of gross yearly revenue.

Q. What is the difference between *product liability insurance* and *manufacturer's errors and omissions insurance*?

A. The product liability section of a commercial general liability ("CGL") policy will defend and pay claims resulting from machines as long as there is attendant physical injury and/or property damage to a third party. A separate policy form is needed to cover claims of indirect or consequential loss, called manufacturer's errors and omissions (ME&O) liability. Though ME&O claims don't occur as often as do product liability claims, they can be more costly. Since any type of product liability claim is potentially devastating to a company, care should be taken to seek out a professional who can quote and explain these different types of coverage in detail.

Q. How does my general (and ME&O) liability coverage respond to lawsuits in a foreign country? Do I only have coverage for a lawsuit brought in the United States and Canada, or do I have true worldwide coverage?

A. While most product liability insurance offers "worldwide" liability, many manufacturers don't realize that there is often a stipulation requiring a suit to be brought in the United States in order to trigger coverage. An international or foreign liability policy can be an inexpensive way to protect against foreign exposure. Such a policy provides coverage in the foreign country where a manufacturer is sued. Take the time to make sure you know what you are purchasing!

Q. What is the difference between *direct* and *indirect damage*?

A. Most insurance companies define *direct damage* to a third party as tangible bodily injury and/or property damage resulting from a machine that has been put to its intended use. *Indirect damage* is consequential loss normally caused by an error or omission in the design of a machine where there may be no resulting physical injury, yet the end user has suffered financial loss (loss of income, loss of use).

Q. Please describe the exclusions on my product liability/completed operations coverage. Is there liability coverage for discontinued machines?

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A. All commercial general liability policies have exclusions. Many of these exclusions are the same from one insurance company to another. Make sure to review the exclusions and assure that the product liability policy provides coverage as broad as that of other available policies. If this is not the case, find out why and ask the agent or broker to explain the differences in language you can understand. Beware of discontinued products exclusion. Some insurance companies will offer product liability coverage but only on machines the company is still manufacturing. Under this exclusion there would be no coverage for a product liability claim resulting from a machine it no longer manufactures. Once again, make sure that you know what you are purchasing.

Q. What will be the role of the insurance broker in the company's risk management program? What will be the insurance company's role?

A. Manufacturers should have a clear understanding of the agent/broker's responsibility, as well as that of the insurance carrier. A manufacturer needs to know from the broker just what the broker's firm will do or not do in terms of being a risk management advisor. In addition to receiving a proposal of insurance coverage and premiums, the manufacturer should request a written overview of the services to be provided and discuss how performance will be measured. Most insurance companies have significant risk control resources available to their policy holders, but all too often these resources are only offered when requested by an agent or broker. Therefore, a written overview should outline specific service functions of the agent/ broker and those of the insurance company, and how the two will assist the manufacturer.

Q. Will an insurance/risk management professional review sales agreements, installation agreements and distributor agreements and provide an analysis of whether my insurance is adequate?

A. Contractual agreements that outline conditions of sale, installations and other service work performed by independent contractors on behalf of a manufacturer are critical documents. Most contain indemnification agreements, hold harmless agreements, waivers of subrogation and insurance requirements. Though an insurance/risk management professional is not an attorney, he or she should be equipped to advise the company what exposures it is assuming by contract and whether the insurance is adequate for the exposure. However, it is advisable to seek advice from your attorneys in these matters as well. For example, states differ in their views on the enforceability of indemnification provisions, and non-attorneys will not appreciate the differences and nuances from state-to-state.

Q. Should I implement a system to monitor the insurance of independent contractors, including distributors, suppliers and installers, to improve my company's protection?

A. Reviewing contracts to determine exposure and insurance adequacy is only part of a risk management system for contracts. Manufacturers should establish certain insurance requirements of all independent contractors (including suppliers) and develop a system to monitor that these requirements are met and kept current. A qualified risk management professional can design an effective insurance plan that will not be administratively intrusive. This plan will reduce the likelihood of a manufacturer's insurance program paying a claim as a result of a third party's negligence. Likewise, to the extent agreements with third-parties, contractors and the like obligate them to provide your company with insurance and/or name your company as an additional insured on their policies of insurance, insist on receipt of both a Certificate of Insurance **and** a copy of the actual policy of insurance as proof that the third party

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has met its insuring obligations. Various courts have held that a mere Certificate of Insurance is not competent proof of the existence of actual insurance.

APPENDIX A - SAMPLE MACHINE INSPECTION CHECKLIST PRIOR TO SHIPPING

Started assembly of machine __ / __ / __

Completed testing __ / __ / __

Date Shipped __ / __ / __

Customer _____

Customer Job No. _____

Manufacturer Job No. _____

1. Risk reduction measures. Using the risk assessment check that all the risk reduction measures listed in the risk assessment have been implemented and have reduced the risk to an acceptable level
2. Electrical – the safety related parts of the control system have been check and tested.
3. Machine manual has been reviewed and is shipped with the machine.
4. Machine nameplate is correct and mounted.
5. Pre-Shipment Photographs - Photograph each machine prior to shipment. Photos should show that all guards and warning labels are in place. The machine serial number or identifier should appear in each photo.

Final inspection for shipment completed by:

(Signature)

(Printed Name)

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APPENDIX B - SAMPLE WARNING LETTER

XYZ Packaging Company
1800 Elm Street
Anytown, USA 12345-6789
(800) 555-1212

Certified Mail / FedEx / UPS

Acme Bottling Co.
600 Maple Drive
Smallville, KS 98765-4321

Attn: Safety Department [or specific name]
Re: Unsafe Conditions/Practices

Dear Sir [or specific name]:

It has come to our attention that your company is permitting to exist an unsafe condition/practice involving equipment supplied by XYZ Packaging Company. [describe unsafe condition/practice in detail]. [Name] verbally and in writing reported the condition to your foreman, [Name].

Corrective action would include but would not necessarily be limited to [describe nature of corrective action], and your employees should be instructed not to repeat [unsafe practice] or allow the [unsafe condition] again.

XYZ Packaging Company's service department is ready and willing to assist you in correcting this unsafe condition/ practice. Please contact us immediately for further details.

Very truly yours,

XYZ Packaging Company

cc: Machine File

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APPENDIX C - SAMPLE SERVICE REPORT

Customer _____

Address _____

Machine model _____ Serial number _____

The machinery listed above has been serviced by _____,
(Name)

a service representative or service technician of _____.
(Company)

Description of service performed:

Does the customer have operating instructions and parts manual for the machinery listed above?
Yes No

If not, does the customer wish to receive manuals for the machinery listed above?
Yes No

Does the customer require any additional training or instruction of its employees in the operation of the machinery listed above?
Yes No

Are all of the safety guards properly installed on the above machinery?
Yes No

Are all of the safety devices properly installed on the above machinery?
Yes No

Are all of the warning labels properly installed on the above machinery?
Yes No

If not, does the customer require a review of all safety guards, safety devices and warning labels, including a quotation for any required?
Yes No

Comments:

The machinery listed above has been serviced and is operating satisfactorily.

Name (please print) Authorized signature

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Title

Date

APPENDIX D - SAMPLE RETROFIT LETTER

XYZ Packaging Co.
1800 Elm Street
Anytown, USA 12345-6789
(800) 555-1212

Certified Mail / FedEx / UPS

Acme Bottling Co.
600 Maple Drive
Smallville, KS 98765-4321

Attn: Safety Department [or specific name]
Re: Newly Developed Guards/Change in ANSI/OSHA

Dear Sir [or specific name]:

As part of XYZ Packaging Company's continuing product development, we are pleased to announce that we have developed a [new] [guard, guards, system] for your [describe machine by model and serial numbers].

Details of the [guard, guards, system] are enclosed.

We believe the [new] [guard, guards, and system] will provide enhanced safety to your employees. The [new] [guard, guards, and system] can be retrofitted to your machine with little disruption to your operations. XYZ Packaging Company will be pleased to supply the parts and labor for this project.

Please contact us immediately for further details.

Very truly yours,

XYZ Packaging Company

cc: Machine File

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APPENDIX E – ADDITIONAL INFORMATION ABOUT WARNINGS

The Importance of Warnings

Warnings protect machine users by conveying vital information about the safe and proper use of the packaging machine and its foreseeable hazards. Warnings are an integral component of any Product Liability Prevention program because adequate and proper warnings may reduce the frequency of incidents or severity of an injury. The importance of warnings is also underscored by the growing variety and complexity of packaging machines and their applications, as well as the need to convey machine-use information to the machine's target markets.

The law imposes a duty to warn in certain circumstances. A packaging or processing machine manufacturer is under a legal duty to warn of a known hazardous condition in the machine. This duty has been articulated by numerous courts and has been codified in state and federal statutes. The manufacturer must keep in mind that its warnings may be reviewed by a judge or jury several years after the machine has been distributed under theories of liability such as negligence and strict liability.

A manufacturer must be careful, however, not to fall into the trap of attempting to "liability-proof" its machines by warning against all types of obvious hazards, thus diminishing the effectiveness of warnings dealing with unknown hazards. Such liability-proofing techniques can result in a profusion of warnings that take away from the likelihood that the important warnings will be read and heeded.

Standards and Warnings

Before discussing the proper content of warnings, it is necessary to understand that warnings have, to a large extent, been influenced by industry or governmental standards.

Through ANSI, machine manufacturers have developed standards for product safety signs and labels (see the latest version of ANSI Z535.4 Standard for Product Safety Signs and Labels). These standards generally represent industry's best attempt at analyzing the current demands of U.S. courts and are accepted by many experts as the most authoritative standards. From a defense perspective, however, these standards should be viewed only as containing minimum requirements, since it is possible that in certain contexts, the warnings may be deemed insufficient to protect a manufacturer even if there has been compliance with the standards. A manufacturer must look beyond the minimum requirements to determine the full scope of its duty to warn others of the potential hazards of its machine.

The standards frequently are very specific about the use of certain words. For example, the ANSI Z535.4-2011 (R2017) standard dictates that the terms DANGER or WARNING should not be utilized for risks to property damage unless the risk of personal injury is also present. However, the word CAUTION or NOTICE may be used to indicate hazards to Property (note that in the 2007 version of the standard the Z535.4 standards committee footnoted its intention to make NOTICE the only signal word to be allowed on labels intended to indicate property damage only hazards in the 2011 version of the standard). The standards also prescribe the colors in which signal words and signal word background panels in warnings should be printed. For example, the word DANGER should be in white letters on a red background, the word WARNING should be in black letters on an orange background, the word CAUTION should be in black letters on a yellow background, and the word NOTICE should be white on a blue background. Safety-conscious packaging and processing machinery manufacturers should become familiar with ANSI Z535.4.

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Some large machine manufacturers, by reason of their research, expertise and experience, have developed standards that are frequently regarded by others as authoritative. However, these standards are subject to change, and like ANSI standards, compliance with them does not

necessarily preclude liability. Although industry standards such as ANSI's are not federal statutes entitled to preclusive effect, they do, by the weight of their authority, effectively take precedence over any other inconsistent standards, at least in the view of many experts and courts.

General Warning Guidelines

Once it is determined that there is a hazard and risk that is not appreciated by the user, and that a warning is called for to address the hazard, the following guidelines for warnings should be followed:

- The warning should command attention.
- The warning should be conspicuous and clearly visible.
- The warning should clearly identify the hazard.
- Warnings should be instructive on the nature of the hazard, the consequence of interaction with the hazard, the seriousness of the hazard and how to avoid the hazard.
- Warnings should convey not only the degree of care required but also the consequences if the warnings are not followed. For example, warnings for a hazardous chemical should describe the specific injury or disease that may result to the "target" organ upon inhalation, absorption or ingestion. Knowledge of the consequences of failure to heed a warning assists the user in understanding the severity of injury that may result from a machine's misuse. That understanding, in turn, assists the machine user in appreciating the magnitude of risk, an important component in product liability prevention.

Courts will generally use a "reasonableness" test for judging the adequacy of machine instructions and warnings. In doing so, courts will look at a number of factors, including: the content and comprehensibility of the warning; the intensity of expression; and the characteristics and knowledge of expected user groups.

How Do You Warn?

Warnings can be conveyed in audible and visual alarms, labels, brochures, manuals, machine enclosures and signs. Good warnings contain five basic elements:

1. Warnings must catch the reader's attention. An inconspicuous or overly detailed warning will not be read. In preparing warnings, the packaging machinery manufacturer must consider human factors, such as a user's fatigue, lack of training and even illiteracy. Techniques to attract the user's attention include the use of bold type, capital letters to emphasize specific words, bright colors in conformance to the ANSI Z535.1 Standard for Safety Colors, borders, and the use of safety symbols (e.g., the skull and crossbones, hand caught in gears, electric lightning bolt). Note that ongoing work is being done within ISO and ANSI to standardize safety symbols in the effort to establish a global basis of communicating specific safety messages.
2. The nature and extent of the hazard must be identified in understandable language. When text is incorporated in a warning, unambiguous, simple English should be used so that the reader can appreciate and comprehend the information. Since it is not possible to include all possible languages in a warning, consideration should also be given to

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alerting the customer who may have non-English-speaking employees to obtain warning signs in other languages. Manufacturers of packaging machines should consider having on hand and available, warning signs in other languages that may be common in a certain locale, such as Spanish.

3. The consequence of failing to follow the warnings must be given. A user unfamiliar with the packaging machine or otherwise lacking knowledge about certain hazards must be instructed as to the magnitude of injury that can result from improper machine use. This warning component makes the risk more comprehensible to the user, in simple terms that are easily understandable. Example: "WARNING: Amputation hazard. Contact with moving parts can result in severe injuries!" is better than "Warning: Moving Parts!"
4. What must be done to prevent injury? Words and symbols are powerful tools in conveying a warning's hazard avoidance information. Best practices typically call for explaining the precise actions to take to avoid the hazard. For instance, the word message noted above, "WARNING: Amputation hazard. Contact with moving parts can result in severe injuries!" may not tell the whole hazard avoidance message. Another line of text may need to be added if maintenance in this area is to be expected. The phrase, "Lockout/Tagout before servicing" would enhance the overall warning because it gives the specific procedure necessary to avoid the hazard.
5. The severity level of the hazard should be indicated. In the ANSI Z535.4 standard the signal words and their respective background colors stand for a specific level of hazard seriousness. The word "DANGER" indicates a hazardous situation which, if not avoided, WILL result in death or serious injury. This word is to be used only in the most serious situations. The word "WARNING" indicates a hazardous situation which, if not avoided, COULD result in death or serious injury. "CAUTION" indicates a hazardous situation which, if not avoided, MAY result in minor or moderate injury.

Formats

Graphical symbols used in place of or in combination with words can be very effective in efficiently communicating safety information across language barriers. It should be noted that ANSI Z535.4-2011 (R2017) standard incorporates the ability to use the ISO 3864-2:2016 Product Safety Label standard as a viable alternative to the formats shown in Z535.4. In practical terms, what this means is that machine manufacturers in the U.S. may now use the international formats and still be in compliance with ANSI. The reference ISO standard, ISO 3864-2, includes "symbol-only" formats that use graphical symbols within colored surround shapes to convey safety messages. The change in the ANSI standards to accept such formats was made as a move towards standards harmonization between national and global standards and its direct effect is that it gives machine manufacturers additional format options to consider when deciding how best to convey their warnings to their intended audiences, national and global. The following chart at the end of this Appendix is useful for evaluating the possible pros and cons of each warnings format.

The figure at the end of this appendix shows some commonly used pictographs. Note, however, that these are simply examples and should not be considered an exhaustive or complete exposition of all warning formats. Consult a safety professional and/or product liability attorney to determine the warnings that are best for your machine.

Whom Do You Warn?

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Warnings should be directed not only to those who purchase the packaging machine but also those to whom the manufacturer may have a legal duty, namely, all foreseeable users. Who is to be warned generally depends on the machine in question. For example, chemicals require detailed and technical warnings contained in Material Safety Data Sheets for the workers who handle them. Household products may have warnings that focus less on the product's composition and more on the need to follow simple instructions. Packaging machines, on the

other hand, can be highly technical in nature, and require warnings intended not only for the operator but for mechanics and repair personnel.

Just as today's manufacturers, especially those with CE marking machinery, are required to maintain technical construction files and the like for their machines, the manufacturer should maintain a technical file for the machine's warnings. Such a file should include data on the process undertaken to select appropriate warnings and all factors considered in the process. Consider subjecting warnings to testing or focus group analysis as further evidence of diligence in the selection of warnings for your machine and including that data in the warnings file.

Packaging and processing machinery manufacturers should also periodically review their warnings to make sure their warnings in comply with the latest versions of all the warning standards (e.g. ANSI, ISO).

Manuals

Ideally, machines would not require manuals to instruct with regard to their potential hazards, operation and maintenance. When a machine does require such a manual, however, the following concepts should be kept in mind from a PLP point of view.

Machine manuals and the warnings appearing on the machine are the packaging and processing machinery manufacturer's tools for conveying accurate and detailed safety information pertaining to the installation, use, maintenance, disassembly and disposal of their machines. Because of their close link, the location and part numbers of all safety labels should be noted in the manual and information on label replacement procedures given. See also requirements and guidance in ANSI/PMMI B155.1 (2016).

On Formatting and Placement

As with warnings, packaging and processing machinery manufacturers should consult the latest standards in the area of manuals and put into place the best practices as defined by the standards. A relatively new standard for conveying safety information in manuals is the ANSI Z535.6 Standard for Safety Information in Collateral Material. This standard, first published in 2006, defines four ways in which safety information is formatted in manuals.

1. "Supplemental Directives" are safety messages that typically appear in the beginning of a manual (e.g. on the cover or first page) or appear at the beginning of a set of grouped safety messages. An example of a supplemental directive is: "Read this manual before operating this machinery. Failure to do so can result in serious injury or death."
2. "Grouped Safety Messages" are typically provided in a separate document or in a distinct section of the manual, often appearing before procedural information.

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3. "Section Safety Messages" typically appear at the beginning of a section or before the procedures to which they apply and help to avoid repetition of the same safety points throughout a procedure.

4. "Embedded Safety Messages" provide safety information in the actual text of the instruction or procedure described in the manual.

The ANSI Z535.6 standard clearly details these format options and gives guidance on when and how to construct safety information so that it can be clearly conveyed to the reader.

Content of Safety Information in Instruction Manuals.

A manual is to be used to instruct the operator of the machine. Consideration should be given to supplying multiple instruction manuals with the machine, especially where multiple operators will be using the machine, and so that a reference copy can be kept on file by the owner. Consideration should also be given to whether the person required to operate the machine will actually have the instruction manual available to him or her and, if so, whether that person can reasonably be expected to review it prior to operation. If the answer to this question is "no," consideration ought to be given to providing instructions with regard to the operation of the machine on the machine itself. If this is impractical or impossible, the manufacturer might consider a warning that safe operation requires a prior review of the instruction manual. In addition, the instruction manual might be chained or otherwise permanently affixed to the machine for this purpose. Of course, if the hazards are significant enough, they should be warned against on the machine, regardless of whether the operator can be expected to review the instruction manual.

When there are hazards to be discussed in instruction manuals, information about these hazards should appear prominently and at the beginning of the instruction manuals. Well-known and accepted terminology such as danger, warning and caution, should be used. Like warnings used on the machines, warnings in instruction manuals should be clear, concise and accompanied whenever feasible by pictographs. If a machine will be used by people speaking a language other than English, the manufacturer should consider using understandable warning symbols or text in language(s) other than English. For this, professional communications and human factors analysis and input may be desirable.

Manufacturers are often tempted to produce one instruction manual for several models of a machine. Such a practice can often lead to confusion. Manufacturers ought to carefully consider whether this potential confusion is advisable if it might reasonably lead to an incident. Generally, a separate hazard/operation / maintenance instruction manual should accompany each model of a machine. Instruction manuals should be dated or otherwise identifiable so that they can be identified with the machine they accompanied and the time/version of distribution. Manufacturers should keep copies of all versions of instruction manuals and, of course, keep records of what versions of instruction manuals were being used at what time with what machines.

Instruction manuals should include information inviting customers to contact the manufacturer for further information or assistance with the machine. Instruction manuals produced by companies with a U.S. presence might provide telephone numbers (preferably toll free), along with an invitation to contact the company by telephone with such inquiries. The rationale for such invitations is to encourage customers to seek information that might avoid incidents. In addition, such invitations can be used to counteract assertions by customers that they were

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somehow confused or had questions about the machine but did not know how to get their questions answered.

On the Preparation/Distribution of Instruction manuals

The concepts addressed in hazard /operation /maintenance instruction manuals are diverse. In any country, it is most unlikely that the engineers who designed the machine will be able to write an effective instruction manual from a PLP point of view. Input needs to be obtained from those familiar with the end user expectations involved in the use of the machine, those who have studied competitors' instruction manuals, those who have studied the claims/incidents/warranty history of the machine, as well as similar machines of their own company and competitors' companies, communications and human factors experts and lawyers.

The typical way machine instruction manuals are prepared is for a instruction manual team to be assembled with people from each of the above- referenced areas. Each participant on the team brings his or her own area of expertise into play. This is particularly important for machines manufactured by people for whom English is not a native language. At the same time, review of instruction manuals by native English speakers is clearly not enough to ensure good communication. The reason for this is that a clear presentation of information requires very careful thought and analysis from a communications point of view.

For PLP purposes, a timeline as to the evolution of the instruction manual can be helpful. Much like a Machine Construction File, a record of the ideas considered for the instruction manual and decisions about what information is included and excluded can aid in defending later challenges to the manual's adequacy. Decisions about what language is used in the instruction manual are ideally based upon studies and objective criteria rather than subjective comments like "it seemed clear to us" or "those of us preparing the instruction manual had no difficulty understanding it."

Finally, make the instruction manual available to users and customers online, with appropriate instructions on how to access the company web site. This information should be contained in the written instruction manual, within the sale documentation and, perhaps, conspicuously displayed in a placard or the like mounted on the machine.



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Product Safety Label Format Options


1. ISO formatted symbol-only:

- **Benefits** – Can communicate across language and literacy barriers, typically uses less space, meets ANSI Z535.4 and ISO 3864.2 standards.
- **Other Considerations** – Comprehension of the symbol's meaning could be an issue, testing/training of symbol meaning may be necessary, typically more than one symbol-only label is needed to communicate both hazard description and hazard avoidance messages, severity of the hazard is not conveyed.


2. ISO/IEC formatted symbol with supplementary text:

- **Benefits** – Text can assist in training on the meaning of the symbol, text can elaborate on the message conveyed by the symbol, meets IEC standards (e.g. IEC 60825 Lasers), meets ANSI Z535.4 and ISO 3864.2 standards.
- **Other Considerations** – Translation may be necessary, severity of the hazard is not conveyed.




3. One or more ISO formatted symbols with supplementary text and ISO/ANSI signal word panel:

- **Benefits** – Meets ANSI Z535.4 and ISO 3864.2 standards, signal word panel conveys severity level.
- **Other Considerations** – Translation may be necessary.



4. One or more non-ISO symbols with supplementary text and ISO/ANSI signal word panel:

- **Benefits** – Meets ANSI Z535.4 and ISO 3864.2 standards, symbol can be reproduced larger without the ISO colored surround shape.
- **Other Considerations** – Use of non-ISO formatted symbol is permitted by ISO but may be an issue for international compliance if an ISO standardized symbol exists for the specific meaning, translation may be necessary.



5. Signal word panel with supplementary text:

- **Benefits** – Meets ANSI Z535.4 standard for U.S. markets.
- **Other Considerations** – Does not meet ISO 3864-2 standard because it does not include a symbol.

▲ DANGER

Hazardous voltage.
Follow lockout procedure before servicing.


or

▲ DANGER

Hazardous voltage.
Follow lockout procedure before servicing.

6. Formats with supplementary text in white on black background:

- **Benefits** – Meets ANSI Z535.4 standard for U.S. markets.
- **Other Considerations** – Does not meet ISO 3864-2 standard – black text and yellow safety alert symbol next to the signal word must be used.




7. Translation format options:

- **Benefits** – All three options shown meet ANSI Z535.4 and ISO 3864-2 standards.
- **Other Considerations** – Need for matching accuracy of translation to intended market/audience, logistics of label installation on products prior to or after shipment, label with English text needed for U.S. market. Note that for use internationally, the supplemental text label shown in lower left needs to be used with a safety label that has a primary symbol (example shown in lower right).

▲ DANGER

Voltaje peligroso.
Antes de dar servicio, seguir los procedimientos de bloqueo.




▲ DANGER

Hazardous voltage.
Follow lockout procedure before servicing.

▲ PELIGRO

Voltaje peligroso.
Antes de dar servicio, seguir los procedimientos de bloqueo.

+



▲ DANGER

Hazardous voltage.
Follow lockout procedure before servicing.

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APPENDIX F – NOTICE OF POTENTIAL LIABILITY INCIDENT

RECORD OF INITIAL INFORMATION

ATTORNEY – CLIENT COMMUNICATION PREPARED IN ANTICIPATION OF LITIGATION

Date & time of injury

Injured Person
Name

Occupation

Nature of injury (describe the severity)

Model/Serial # of Machine

Description of machine that caused injury

Detailed description of activity when injury occurred

Is machine available for identification and visual examination?

Yes No

Location of machine

Customer Who Purchased Machine Involved in Claim
Name

Address

Phone

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Primary contact person with information about the incident

Name

Address

Phone

Person Who Contacted Manufacturer

Name

Address

Phone

Address where injury occurred

Witnesses to Incident

Other Facts that may be pertinent/useful. Do not speculate or guess. Be factual.

Name (please print)

Authorized signature

Title

Date

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Forward this information to your insurance company and agent as soon as possible. Prompt action and investigation can often resolve claims short of open confrontation leading to litigation.

GLOSSARY OF TERMS

These definitions are not legal definitions, but rather definitions written for laymen to assist in their understanding of the product liability legal system. If legal use is required, consult an attorney.

Assumption of risk - A risk of harm knowingly and voluntarily assumed by the complaining party.

Comparative negligence - A doctrine designed to ameliorate the harshness of contributory negligence, which completely bars recovery. The jury determines the total damages and the percent of total negligence (fault) attributable to the plaintiff. The award is then reduced by the percent of the plaintiff's negligence. Some form of comparative negligence has now been adopted by 34 states.

Compensatory damages - Damages that will compensate the plaintiff for the injury sustained.

Contributory negligence - A doctrine, which if the plaintiff is negligent, completely bars recovery by the plaintiff.

Deposition - The taking of pertinent testimony, not in court but under oath in the presence of attorneys for the plaintiffs and the defendant. The deposed person may be anyone with knowledge of the plaintiff's injury or the allegedly defective machine in question. The testimony is intended for discovery and/or preservation of evidence.

Discovery - Investigation of the facts of a claim and/or the alleged proximate cause of injury. Discovery may include interrogatories, deposition, expert examination of the machine in question and the plaintiff's medical history.

Interrogatories - A series of formal written questions propounded by either party to a legal action and served on the adversary for the purpose of discovery. The questions must be pertinent to the case and must be answered, except where objected to by counsel for legal cause. Such questions and answers are normally filed with the trial court. They can be used at the trial, especially for impeachment purposes.

Liability - The state of being bound or obliged in law to do, pay or make good something. With respect to tort law, liability is usually based on the law of negligence.

Negligence - Failure to do something that a reasonable person would do or doing something that a reasonable and prudent person would not do.

Punitive or exemplary damages - Damages awarded the plaintiff in excess of compensatory damages to punish a defendant for willful or wanton disregard of user safety or by reason of alarming conduct by the defendant. Although liability insurance usually includes punitive damages coverage, the law in some states prohibits payment by insurance companies as being against public policy.

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State of the art - Applicable technology or design criteria known or available to the manufacturer at the time a particular machine was manufactured.

Statute of limitations - A limitation on the elapsed time from the date of injury during which the injured party can file suit. Though the statute in most states is either two or three years, in others it may run from one to six years. In the case of minors, the statute runs from the date they reach legal age.

Statute of repose - A limitation on the elapsed time from the date a machine is manufactured or first sold to a user during which a user can sue claiming injury by that machine. Relatively few states do not have a statute and the time varies from six to twelve years. However, the statute may make provision for certain extenuating circumstances.

Strict liability - A modification of the law, as based on negligence, in which under certain facts, the defendant can be found liable without proof of negligence.

Subrogation - The substitution of one person in place of another with respect to rights, claims or securities. Subrogation is often used by insurance companies under their contract of insurance in which they substitute themselves for an injured party who has been paid by the insurance company and who has a valid claim by reason of an injury or damage.

Tort - A wrong or wrongful act.

Tortfeasor - A wrongdoer; one who is guilty of a tort or wrong.

Warranty - A representation, express or implied, referring to the character or quality of an item sold in the stream of commerce.

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