



US EXPORTS

# GUIDANCE FOR EXPORTING TO THE USA

A PRACTICAL GUIDE TO PRODUCT  
LIABILITY ISSUES IN THE USA



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# GUIDANCE FOR EXPORTING TO THE USA

## 1. Introduction

**For many companies, exports to the USA present significant potential with regard to the future sales of their products and a quick review of some headline figures explains why . . .**

In terms of GDP, the US is the world's largest economy<sup>1</sup> AND the largest importer of goods and services<sup>2</sup>.

The UK is the 6th largest importer to the US, worth a staggering \$48 billion per annum<sup>3</sup> to UK companies.

This consumer led, free market offers potentially huge opportunities to UK based exporters.

### 1.1 So what's the problem?

Liability claims exceeded \$254 billion (£168 billion) per year in 2008<sup>4</sup>. This is more than the US government spend on education, transportation, justice, agriculture and energy combined<sup>5</sup>. This equates to \$838 per man, woman and child in the US and actually represents 1.7% of the gross domestic product<sup>4</sup>.

Due to a number of contributing factors, the country represents potentially one of the most litigious environments in the world.

It is our experience that few companies consider the elevated product liability exposure that these exports represent, often assuming that a "safe" product in the UK is the same as a safe product in the US. This isn't always the case.

The increased liability exposure comes from many sources, some of the more prominent factors are briefly described below:

- There is an increased likelihood of a claim due to the litigious nature of the territory.
- US product liability claims may be based on one of the following:
  - breach of warranty
  - negligence
  - strict liability.
- The ability to bring claims under theories of strict liability removes the need for plaintiffs to demonstrate negligence on behalf of the manufacturer. Strict liability cases revolve around whether the "injury" was a result of a defect in the product, and whether that defect was in existence when the product was sold by the manufacturer. Insufficient warnings regarding hazards posed by the product can be treated as a product defect.
- Plaintiffs' lawyers often employ a "scattergun" approach to citing defendants, calling even upon parties only peripherally involved in an incident to defend the claims, and thereby increasing the potential damage pool. Under the US doctrine of joint and several liability, a claimant can recover from multiple defendants collectively, or a single defendant alone.



- In the US, insurers have a statutory duty to defend a claim. Even in cases where the defendant is victorious, defence costs can be enormous because of the complexity of the arguments, the number of experts required, and the nature of the US legal process.
- Some people believe that there can be a reduced level of proof/causation required by a plaintiff in order to secure an award in the US when compared with the UK.
- Juries (instead of Judges) usually make decisions on liability and also set the level of awards.
- Potentially enormous damage awards can be made. For example according to a Bloomberg report, in 2009 there was a \$300 million judgment against Altria's Philip Morris unit in Florida state court, and five of the 50 biggest US verdicts in 2009 involved claims of defective goods.

We suggest to any of our clients who export to North America that, given the nature of the US legal environment, there is a substantial risk that at some point in time they will become involved in, and find it necessary to defend, a US based product liability suit.

Because of the risk that parties involved in the business of selling or distributing products in the US will be held liable for harm caused by a defect in that product, it is prudent for them to undertake a pro-active approach. Developing a "defensive strategy" to dealing with lawsuits can significantly reduce your financial exposure. The earlier such a strategy can be put in place prior to US distribution, the more effective the protection it can afford.

As previously noted, defence and other costs can escalate rapidly. Accordingly, it is also important for defendants to be prepared to respond quickly and effectively when lawsuits arise. In most instances, the better prepared you are, the more likely you are to avoid extreme legal entanglements and expense.



## 2. Legal system overview

**The US legal system itself is founded upon the principle that each and every person, regardless of economic means, should be allowed access to the system and to have their complaint heard and acted upon.**

In the UK, the legal expense of bringing an action can discourage frivolous suits. However, many attorneys in the US operate on what is known as a “contingency fee” basis whereby a Plaintiff attorney will take on a case on the basis of “no win, no fee.” The amounts at stake can be truly enormous; many US lawyers have become quite wealthy through the use of such contingency fees. They don’t get paid unless they can collect an award, and this encourages them to target as wide a potential defendant base as possible in order to ensure the biggest potential recovery pool possible. This is known as the “shotgun” or “scattergun” principle. As each defendant must defend himself against the action the impact on overall legal costs is significant.

“Many US lawyers have become quite wealthy through the use of contingency fees.”

Although some onlookers have argued that under such circumstances an attorney should be less likely to take on a products liability case unless he sees a reasonable chance of winning, the fact of the matter is that an attorney can still make a fairly good recovery even when a case is weak because many defendants may be willing to settle for the “nuisance value” of the case, which cumulatively could still be substantial.

### Overview of the US legal system

The fact is that when a product is sold into the US market the manufacturer/distributor is bound by the laws operating there. In order to better comprehend the US legal system, a brief overview may be helpful.

There exist two separate court systems in the United States; a Federal Court System and a State Court System. While the fundamentals of operation and procedure are essentially the same in either system, they are established in separate and distinct ways and may function somewhat differently. Most US defence attorneys recommend that their clients try to avoid being tried in state courts if at all possible, because federal courts and juries are considered to be less sympathetic to plaintiffs.

## 3. Product liability law

**The following outline is intended to provide a general understanding of the basic product liability law as it applies in the US. It is not meant to be a legal discourse and anyone involved with the marketing of a product in the USA is strongly advised always to seek appropriate professional legal advice.**

In general, any manufacturer who places a product on the US market, irrespective of his country of domicile, has a non-transferable legal obligation to supply a “safe product”.

In designing a “safe product” in accordance with this definition, the manufacturer is expected to have:

- complied with all of the applicable US National and Industry Codes and Standards and Product Safety Laws as an absolute minimum,
- independently evaluated any risks reasonably associated with the product and anticipated all of the hazards arising from both the intended uses and “foreseeable misuses” of the product. (This “foreseeable misuse” obligation may be considerably broader in the US than the requirements of most other territories to which a product is exported),
- provided adequate warnings, labels and documentation.

### 3.1 Manufacture to customer specification

It should not be assumed that, just because a product has been manufactured and supplied in accordance with a customer’s specification, the manufacturer is absolved from any legal liabilities. He must still take reasonable steps to ensure that the product will be safe in use and to advise his customer of any potential difficulties.

In this context, the application of the “reasonable” standard will be in accordance with US caselaw.

### 3.2 “Strict” Liability

In order to hold a defendant liable on the basis of strict liability, the jury must find that, based upon the evidence, the product was defective and unreasonably dangerous at the time it left the possession and control of the manufacturer. On this basis, the jury is directed to focus on the product itself, irrespective of whether the manufacturer was negligent in making the product.

In defending against such a claim, it is important to focus the jury on the date that the product was manufactured, not on the date of the incident, which could be years later. Custom and practice in the industry, state of the art with respect to technology available, and compliance with standards and regulations form a basis for the defence of this type of claim.

A strict liability claim is generally considered to be the “easiest” type of liability to prove, because a product can be found to be defective and unreasonably dangerous under the law without needing to prove that a manufacturer has been negligent; on the other hand, a manufacturer cannot be proven negligent without first proving that the product is defective and unreasonably dangerous.

### 3.3 Negligence

The fundamental legal definition of negligence is based on the following two premises:

1. The manufacturer owes a duty to produce a reasonably safe product;
2. The manufacturer breached that duty.

The defence in a negligence claim becomes more personalised than that in a strict liability claim. The conduct of the engineering staff in developing the product, the research and testing of the product by the manufacturer, and the effort of the manufacturer in attempting to market a product that is reasonably safe are all to be considered. Furthermore, the knowledge of the manufacturer plays a part in a negligence claim, whereas in a strict liability claim it does not. If a manufacturer does his best to produce a safe product, and does not have knowledge of some unsafe aspect that is likely to cause injury and was not foreseeable, then the manufacturer is unlikely to be held to be negligent.

### 3.4 Causation

In order to find a defendant liable for damages to a plaintiff, not only must the jury find strict liability and/or negligence, they must also find causation.

Causation is a finding that the negligence or defect in the product was a cause of the particular injury claimed by the plaintiff.

A manufacturer can be found to be negligent and a product can be found to be defective, but if the jury finds that the negligence or defect was not a cause of the plaintiff's injury, then there is no liability.

### 3.5 Plaintiff's Contributory or Comparative Negligence

In some US states, a claimant will be barred from recovery if his own negligence caused or contributed to his injury; this is known as contributory negligence. Most jurisdictions, however, apply a standard of comparative fault, where a claimant's recovery may be reduced or even eliminated depending upon the extent to which the claimant's own negligence contributed to his injury. Knowing how these standards will be applied in a given jurisdiction is important in defending a claim.



### 3.6 Damages

In addition to making a determination as to liability and causation, the jury is also responsible for determining the amount of damages that a plaintiff has incurred as a result of his injuries.

Damages are broken into two types:

#### 3.6.1 Compensatory

These are the damages that are determined by the jury to compensate the plaintiff for his injuries. They typically include “economic” damages for medical bills and past and future wage loss, and “non-economic” damages for pain, suffering, inconvenience and disability.

The “economic” damages are generally well defined, and usually are not the subject of great disputes at trial. The “non-economic” damages, however, are not well defined. The jury is required to assign an amount to compensate the plaintiff for his pain, his suffering and the like. This area of damages is directly affected by the way in which the defence of the liability case is put to the jury. If the jury does not believe the defendant's case, or is upset with the defendant for its conduct during trial, this amount will be much higher than if a good defence is presented. This amount is also affected by any degree of sympathy that the jury might feel for the plaintiff.

“Non-economic” damages are not punitive damages, but if a jury does not like the defence of the case as presented by the defendant, this amount can take on some of the characteristics of punitive damages.

### **3.6.2 Punitive Damages**

These damages can only be awarded against a defendant under circumstances where the jury finds that the conduct of the defendant was so grossly negligent or malicious that an amount is determined by the jury to punish the defendant. It is up to the trial court judge to determine whether punitive damages get submitted to the jury at all; a proper defence limits the likelihood that they would even be submitted to the jury for consideration. In the event that punitive damages are submitted, the jury must assign an amount of money that they feel will punish the defendant to the extent that such conduct will not occur in the future. Punitive damages have received a great deal of attention as they have often been the cause of some of the very large court awards made in recent years. They are a real threat to a defendant in that, in most cases, they are uninsurable under US policies. Some states specifically prohibit the insurance of punitive damages and most US insurance policies will exclude them in any case. They are treated in much the same way as a penal fine against the defendant.

The best defence to punitive damages is to present a strong, personal defence that lays the basis for the court to strike any punitive damage claim before it is submitted to the jury. There also exists the fundamental law that punitive damages require a finding of negligence as a basis, as they are founded on the conduct of the manufacturer, and cannot be assessed on the basis of strict liability alone. While several jurisdictions allow punitive damages in strict liability, many jurisdictions require a negligence finding as a pre-requisite to any punitive damage claim. It is important early in any products liability case to clearly define the stance on punitive damages adopted by the law of the state in which the case is pending. Once the law is known, the evidence necessary to defeat such a claim can be appropriately presented.

### **3.7 Appeal**

An adverse verdict at the trial court level is not necessarily the end of the case. Both parties are afforded the opportunity to appeal the case to a higher court to have an adverse result overturned or the level of award modified.

### **3.8 Types of claims brought by plaintiffs**

The plaintiff, in order to recover damages from a defendant, must bring his case under the law as outlined above. The plaintiff has the burden of proving his case by a preponderance of the evidence. (Punitive damages must generally be supported by clear and convincing evidence, which requires a showing by the plaintiff that the conduct of the manufacturer is not merely negligent, but is so outrageous and reckless that it ought to be punished).

In order to fit within the law as outlined above, a plaintiff will generally fit his/her claims into one of the four following types:

#### **3.8.1 Negligent/defective design**

Most products liability cases involve this type of claim. The plaintiff claims that the product was defective and the manufacturer was negligent because the design of the product did not include some safety device or system that would have prevented the accident. Interlocks, safety equipment, warning alarms and the like fit into this category.

#### **3.8.2 Negligent/defective manufacture**

Relatively few products liability cases involve this type of claim, as these generally result under circumstances where the product fails causing injury. A weld failure, or cylinder failure would be common examples of this type case. These cases are somewhat more difficult to defend because a manufacturer needs to explain how the product failed and why. Product failures generally result from misuse, abuse and/or lack of maintenance and inspection.

#### **3.8.3 Failure to warn**

Most product liability cases will include this claim in addition to a defective design claim. The plaintiff will claim that either in addition to or as an alternative to the omission of some safety device, the manufacturer should have provided a specific warning to the plaintiff. The plaintiff further claims that the warning would have been followed by the plaintiff and that by following the warning the accident would have been prevented.

This type of claim is often based upon a fair amount of speculation and conjecture, and would need to be defended with a human factors or warnings expert recognised in the field of warnings and instructions.

#### **3.8.4 Post-sale duty to warn or retrofit**

Under this type of claim, the focus is shifted from the date the equipment left the possession and control of the manufacturer to the date of the injury. The plaintiff will contend that even if the product was not defective when it left the possession and control of the manufacturer, and that the manufacturer was not negligent at that time, the knowledge gained by the manufacturer between the date of manufacture and the date of the injury should have required some additional warning and/or some additional retrofit of a safety device to protect the plaintiff. The plaintiff will contend that the failure of the manufacturer to retrofit with a safety device or additional warning is negligence.

Note that under this type of claim the plaintiff should not be allowed to recover under the theory of "strict" liability; this claim is based purely on the conduct of the manufacturer.

<i>Claim</i>	<i>Negligence</i>	<i>Strict Liability</i>
Design	X	X
Manufacture	X	X
Failure to warn	X	X
Post sale duty	X	

With this general overview of the products liability law in the United States, it is possible to evaluate and implement a comprehensive products liability loss prevention programme.

### 3.9 Defences

#### 3.9.1 Negligence

There are a number of defences to a claim of negligence. These include:

- The plaintiff's injury was not reasonably foreseeable.
- The seller did not breach its duty in that the design, manufacture or marketing of the product were reasonable under the circumstances.
- The plaintiff did not sustain a compensable injury: e.g. a false claim has been lodged, or the injury has not physically occurred and so cannot be legally recovered (e.g. the plaintiff has not developed cancer but fears that he or she will in the future).
- The plaintiff's injury was not 'caused' by the seller's negligence: the plaintiff sustained their injuries from something other than the product supplied.
- The seller complied with relevant industry standards and customs and practice. Caveat: A defendant normally may introduce evidence that it complied with applicable industry standards and customs to show that it exercised reasonable care in the design, manufacture or marketing of its product. However, compliance with industry standards and customs does not automatically absolve the defendant from liability. The jury weighs that evidence together with other evidence presented) in deciding whether the care exercised by the defendant was sufficient under the circumstances.
- The plaintiff was partly to blame for the incident (i.e. Contributory Negligence): a manufacturer may minimise its liability by proving that the plaintiff was partially at fault for the injury. Although specifics vary from state to state, a plaintiff generally cannot recover against a defendant if the jury finds that the plaintiff is more at fault than the defendant. Even if the plaintiff is less at fault, the plaintiff's recovery usually is limited by the extent of his or her own negligence. Thus, if the plaintiff is 20 per cent at fault and the defendant is 80 per cent at fault, the plaintiff's recovery may be reduced by the amount of his or her own negligence, or 20 per cent.

A plaintiff may be deemed to be at fault if:

- The plaintiff failed to exercise reasonable care in the use of the product.
- The plaintiff misused of the product; or
- The plaintiff failed to read or follow warnings or instructions.

#### 3.9.2 Strict liability

As discussed, strict liability claims can be more difficult to rebut as they focus on the product and not the actions of the supplier. However, a defendant may defeat a strict liability claim by challenging the evidence that the plaintiff has presented in support of the claim. The defendant may use similar rebuttal as used in negligence claims (such as product misuse, contributory negligence etc. However, in addition, a defendant may benefit from any of the following arguments:

- **The product was modified after it was sold:** it's important to note that alteration or modification may not relieve the seller from liability if that alteration or modification was reasonably foreseeable and the seller failed to account for the risk (such as warnings).
- **State of the art:** a seller may demonstrate that its product employed the current technology and know how that was available at the time the product was manufactured. Improved technology and information that was not available or feasible for use until after the product was sold, thus removing the plaintiffs allegations that the product was defectively designed at the time it left the seller's control.
- **Industry custom, industry standards, and government standards:** a seller may also be allowed to introduce evidence that its product complied with industry standards or custom in the industry to rebut the plaintiff's claim that the product was defectively designed.



#### 4. Some key elements of the legal process

**For a more detailed description of the legal process, professional advice should be sought. Suffice it to say that the correct process must be followed by the plaintiff for a legal action to have status in the courts. Similarly, the defendant must also abide by the rules of the legal process in order to mount an effective defence. For example, failure to respond to an action can lead to a default judgment for the plaintiff with no subsequent right on the part of the defendant to contest the finding.**

Although it is not the intention of these guide notes to go into detail about the US legal process there are a few unique elements of the process that merit further discussion, namely:

##### 4.1 Discovery

The discovery process is that part of the US legal process whereby the parties are required to provide information relevant to the dispute to the opposing counsel with limited rights of reply or cross examination. This part of the process can also apply in territories outside of the USA, such that a UK/Europe-based defendant could become involved in giving a deposition in the UK.

Formal discovery has several aspects, including asking and responding to questions known as interrogatories, seeking and turning over documents related to the action, asking the other side to admit to certain facts, and taking depositions. Depositions are formal question-and-answer proceedings that are taken down by a court reporter, and often a videographer, for use later at trial. Toward the middle portion of formal discovery, depositions are taken of percipient witnesses - those witnesses who have knowledge or have perceived something related to the incident. Toward the end of formal discovery, depositions of experts occur. These are witnesses hired by one side or another to provide opinion testimony on subjects like medicine, accident reconstruction, safety, design, and other areas. The formal discovery process in a case can last quite some time. Depending upon the complexity of a case, formal discovery can last from three months to several years.

There are rules governing the types of documentation which are “discoverable” and those which are not, and this is closely linked both with the relevance of the document to the case and to the extent to which documentation is protected by the “Attorney-Client privilege”. The latter principle is essentially designed to protect the confidentiality of the communication between a client and his attorney. Whilst important, it has its limitations and, once again, is a complex area of law in its own right in which specialist professional guidance is vital. It is imperative that any defence responses to discovery requests be made with the active input of a Defence attorney who is fully aware of the

“It is imperative that full product safety documentation is kept ready for inspection and that documentation procedures are effective.”

relevant US law, as responses made at this stage can have a significant bearing on the outcome of the case.

Discovery can be quite onerous from both a workload perspective and because US law does not permit the making of any alterations to, or removal of data from, documents being produced. This means that, if they exist, even potentially damaging documents, file notes or “asides”, whether positive or negative, must all be made available to the opposing side. Suffice it to say that the information or the lack of information uncovered in the discovery process can be pivotal in the success of a product liability action. It is, therefore, imperative that full product safety documentation is kept ready for inspection and that documentation procedures (including a formal and properly established Document Retention Policy) are effective. Compliance with the requirements of an ISO 9000 certification scheme can often go some way towards providing this level of documentation.

##### 4.2 Court/out of court settlement

Most lawsuits filed in the US do not actually reach court. Many plaintiff cases falter either because there are insufficient grounds for the case to proceed or because the plaintiff attorney decides that the likely probability of success does not justify continuation. Many cases are settled “on the court steps”.

One reason for this is that if a case does actually get into court then the costs start to escalate and the stakes become much higher. With few exceptions, US courts are public domain; the case, its handling and the names behind it become public knowledge once the court sits. It is at this point that the reputation of the defendant and his products may become seriously exposed.

Another consideration arises if any representatives of the management of the defendant company are actually called to give evidence either by the plaintiff or defence side. As the court will obviously be sitting in the US, the travelling and time costs involved can be significant. Furthermore, it is not uncommon for hearings to be deferred several times on technicalities.



## 5. Product integrity programmes and defensive strategies

**By undertaking a pro-active approach and developing a “defensive strategy” to deal with a lawsuit, significant exposures can be controlled. The earlier such a process can be put in place in a products lifecycle, the more robust the protection it can afford.**

*Elements of a product integrity programme*



The key features of such a strategy would include:

1. Research relevant standards and document compliance or (perhaps more importantly) reasons for any necessary non-compliance. If a product is deemed non-compliant with mandatory standards without good reason, the case may prove to be un-defendable. The company must exhaustively research all statutory regulations (such as FDA, OSHA etc), recognised voluntary standards (such as ANSI, ASME etc), and all customs and practice applied by your industrial peer group (i.e competitors) that would have an effect on the safety of your product. Demonstrable compliance with all of the above should be deemed as a minimum requirement.
2. Appropriately document safety evaluation for the products.
3. When considering safety functions, it is important that a single design configuration is manufactured for both US and non-US exports. Omitting safety functions on US exports in order to comply with US standards is not an acceptable practice.
4. **ACE strongly recommends that legal advice be sought from a US based attorney who understands your products.**
5. Ensure that all documentation is clear, concise and free of opinion and comment that might be used against your company in a US court. A plaintiff attorney can require a wide range of information relating to the product to be made available to in the event of an action being brought. This is known as “discovery”. (It must be noted that it is a Federal offence in the USA to modify or delete information after a Discovery request has been made, so forward planning is vital).
6. Ensure that appropriate warning labels are provided on products and that these labels conform to the regulatory or industry standard, as well as voluntary codes. Important voluntary standards would include ANSI Z 535.4. The associated decision making process should be fully documented (particularly where labelling is not provided or is not in accordance with the ANSI standard). It is strongly recommended that expert advice be sought with regard to the process of ensuring that warnings and labels used are of sufficient standard. Alleged deficiencies in warnings and instructions that accompany products are estimated to be included in as many as 80% of all product liability cases<sup>6</sup>.
7. Ensure that the product/user instruction manuals are kept up to date and documented.
8. Ensure that advertising material is consistent with other documentation such as instruction manuals, and there is no contradiction within the literature on issues relating to safety.

*Example of ANSI Z 535.4 label*



## 6. US export checklist



1	Research all relevant standards and have documented compliance or (perhaps more importantly) reasons for any necessary non-compliance.	
2	Document all in house risk assessments and test results for the products.	
3	Try to ensure that the safety functions on a product are common regardless of the territory in which it is being marketed. Omitting safety functions on US exports in order to comply with US standards is not an acceptable practice.	
4	Obtain specialist US legal advice relating to your product and product development system. Retain the services of a US based attorney who understands your products.	
5	Ensure that all documentation is clear, concise and free of opinion.	
6	Where the most appropriate control is deemed to be a warning/label (i.e. where the risk cannot be designed out or guarded against), ensure that the labels used clearly indicate: <ol style="list-style-type: none"> <li>1. The nature of the hazard</li> <li>2. The level of seriousness of the hazard</li> <li>3. The likelihood of the hazard resulting in harm</li> <li>4. How to avoid the hazard</li> <li>5. The consequences of the hazard if the warning is not heeded.</li> </ol>	
7	Ensure that appropriate warning labels are provided on products that these labels conform to the regulatory or industry standard. Important voluntary standards would include ANSI Z 535.4.  The selected standard and the associated decision making process should be fully documented (particularly where labelling is not provided or is not in accordance with the ANSI standard). It would be strongly recommended that expert advice be sought with regard to the process of ensuring that warnings and labels used are of sufficient standard.	
8	Ensure that the product/user instruction manuals are kept up to date and documented. Place most up to date manuals online.	
9	Ensure that advertising material is consistent with other documentation such as instruction manuals, and there is no contradiction within the literature on issues relating to safety.	
10	Consider how you may fulfil your post sale duty to warn: <ul style="list-style-type: none"> <li>• Complaints Monitoring</li> <li>• Configuration Control</li> <li>• Use of warranty data, customer databases, online solutions etc.</li> </ul>	

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## CONTACT US

### ACE European Group Limited

ACE Building  
100 Leadenhall Street  
London EC3A 3BP  
Tel: +44 20 7173 7000  
Fax: +44 20 7173 7800  
[www.acegroup.com/uk](http://www.acegroup.com/uk)

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