



FOLEY & LARDNER LLP

FOOD & BEVERAGE

Supply Chain Desk Reference

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BATTLE OF THE FORMS

Natalie Neals and Ryan Riffle

I. What is a “Battle of the Forms”?

- A. A “battle of the forms” occurs when a seller and a buyer in a transaction involving tangible goods exchange standard forms. These forms usually contain terms that are in addition to, or are different than, the terms in the other party’s form. For example, a buyer submits a purchase order with small-print terms and conditions of purchase printed on the back. In response the seller wants to accept the order but does not want to agree to the fine print, so it sends back an order acknowledgment that includes its standard terms and conditions of sale.
- B. This common scenario becomes an issue under Article 2 of the Uniform Commercial Code (the “U.C.C.”). Article 2 states that any definite and seasonable expression of acceptance, or a written confirmation, sent within a reasonable time after a sales offer has been sent can constitute acceptance of an offer, even if the two documents contain different terms. U.C.C. § 2-207(1).
- C. When the forms contain different terms, the “battle” occurs to determine which terms will control. Terms that conflict are knocked out and replaced with U.C.C. gap-fillers. U.C.C. 2-207(3).
- D. Additional terms (new terms in the acceptance that do not contradict a term in the offer) become part of the agreement unless (1) the offer expressly limits acceptance to the terms of the offer; (2) the additional terms materially alter the agreement; or (3) the party making the offer has already given notice of objection to the terms, or objection is given within a reasonable time after notice of them is received.
- E. If the acceptance or confirmation is expressly conditional on the agreement of the party that made the offer to the additional or different terms, the acceptance/confirmation is deemed to be a counteroffer, and no written contract is formed. A contract may then be created by the conduct of the parties recognizing that a contract exists (typically delivery of the product by the seller and acceptance thereof by the buyer). The terms of that agreement are any terms on which the forms of the parties agree, plus any “gap-filler” terms from Article 2 of the U.C.C. A court can apply gap-filler terms for everything except the identification of the goods themselves and the quantity. Most of the gap-filler terms are highly buyer-friendly (for example, warranties implied by law into the contract and unlimited damages for breach).
- F. Not taking proper consideration of the “battle of the forms” can result in inconsistent results and agreement to onerous terms.

II. Practical Ways to Deal with Battle of the Forms as a Seller.

- A. Make sure your standard documents include the “Magic Language.”
Failing to include this language could mean that the seller is accepting the properly submitted terms and conditions of the buyer.

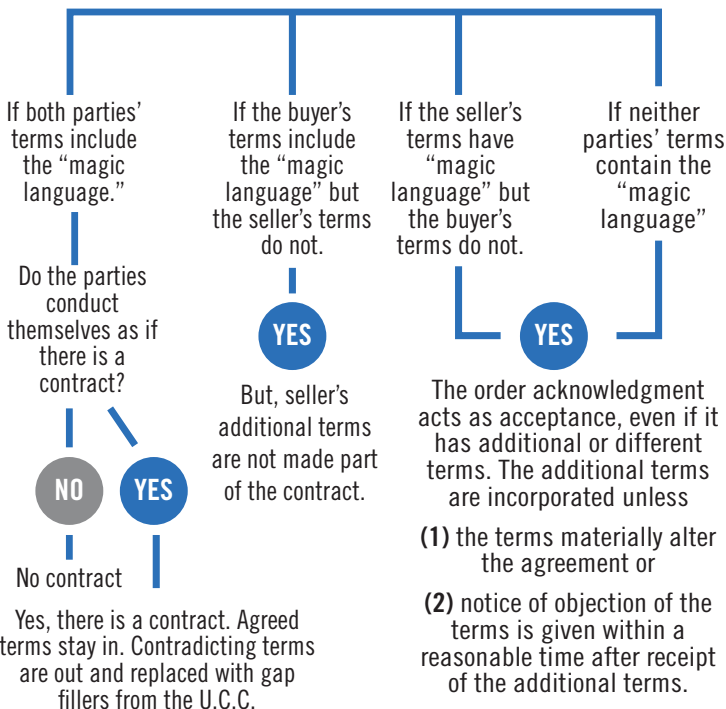
EXAMPLE "MAGIC LANGUAGE":

"Offer. This document is an offer or counter-offer by Seller to sell the goods and or services described in it in accordance with these terms and conditions, is not an acceptance of any offer made by buyer, and is expressly conditioned upon buyer's assent to these Terms and Conditions of Sale. Seller objects to any additional or different terms contained in any request for proposal, purchase order, or other communication previously or hereafter provided by buyer to Seller. No such additional or different terms or conditions will be of any force or effect."

- B. Always read agreements and forms carefully and make sure that the terms are acceptable before signing or sending back a conflicting standard form. Timely object in writing to any terms that are not acceptable.
- C. Do not sign buyers' forms. Encourage buyers to sign your forms. Do not make reference to buyers' forms in any correspondence.
- D. In internet sales, require buyers to click to accept your terms of sale in order to be able to place an order.

Common Scenario: Buyer sends seller a purchase order with its terms and conditions. Seller sends back an order acknowledgment with its terms and conditions.

IS THERE A CONTRACT?

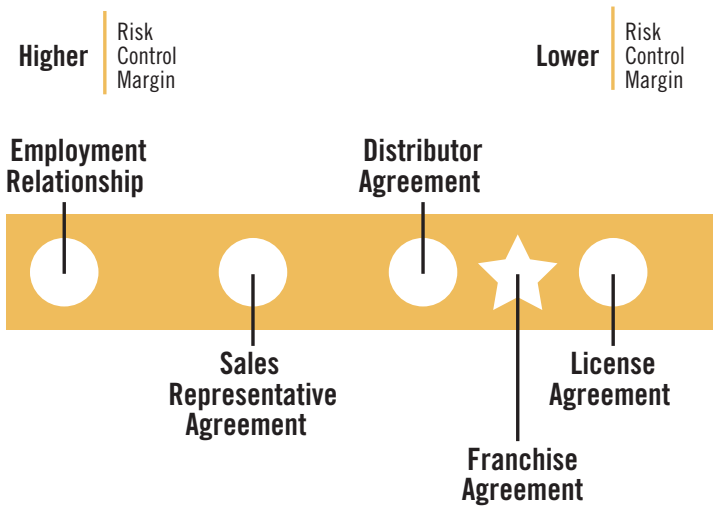


DISTRIBUTION SUPPLY CHAIN OPTIONS

Kate Wegrzyn

When determining how to sell a product in the marketplace, there are a number of supply chain options from which to choose, each with its own set of legal implications. However, the primary consideration in determining how to sell a product should be what makes the most sense from a business perspective (for example, if the product requires, a large physical inventory, having these responsibilities outsourced to a distributor may be the most practical solution).

Here is a high-level summary of the common ways to sell product:



I. Employee (Vertical Integration).

- A. Overview.** Supplier employs salespeople to sell the product directly to the ultimate customer. The costs associated with this structure are higher, as more resources are needed to implement it. The margin tends to be higher because there is no intermediary.
- B. Compensation.** The employee is paid a salary (which may be commission-based).
- C. Credit Risk.** Supplier bears the credit risk as to the ultimate customer (that is, if the ultimate customer does not pay, Supplier is not paid).
- D. Control.** Supplier retains the relationship with the ultimate customer and has complete control over the sales activities, including pricing.
- E. Termination.** Termination follows local labor laws. In most states in the United States, the employee may be terminated at will.

II. Sales Representative Agreement.

- A. Overview.** Supplier contracts with an independent contractor, who solicits orders for the product from the ultimate customer and passes those orders on to Supplier. Supplier is able to accept or reject the orders, and accepted orders are contracts between the Supplier and the ultimate customer.
- B. Compensation.** Supplier pays a commission to the sales representative, which is often a percentage of the invoice value of the accepted orders that the sales representative solicited and the supplier accepted.
- C. Credit Risk.** Supplier bears the credit risk as to the ultimate customer. (If it is unclear if the relationship is one of a distributorship or a sales representative, this factor will likely be determinative.)
- D. Control.** Supplier retains nearly-complete control of the sales activities, including pricing. However, the sales representative may have the personal relationship (but not the legal relationship) with the ultimate customer.
- E. Termination.** A few jurisdictions have statutory protections against terminating sales representatives, but, in large part, termination is unrestricted by law, provided that the sales representative is paid timely for any outstanding commissions.

III. Distributor Agreement.

- A. Overview.** Supplier contracts with a distributor, who purchases the product from the Supplier for re-sale in the contractually-prescribed territory. Many states have statutes requiring that the Supplier compensate a distributor for warranty work done by the distributor at statutorily-prescribed rates.
- B. Compensation.** Distributor resells the product at a markup, with such profit being the distributor's only compensation.
- C. Credit Risk.** Distributor bears the credit risk as to the ultimate customer. Supplier bears the credit risk as to the distributor.
- D. Control.** Supplier's control of the sales activities (including pricing) is limited by antitrust and other principles. Further, the distributor maintains the personal and legal relationship with the ultimate customer.
- E. Termination.** The termination or non-renewal of a distributor is often restricted by statute (particularly in certain industries, like motor vehicles, industrial or construction equipment, and agricultural equipment), and may require the buy-back of inventory or may prohibit any termination without good cause.

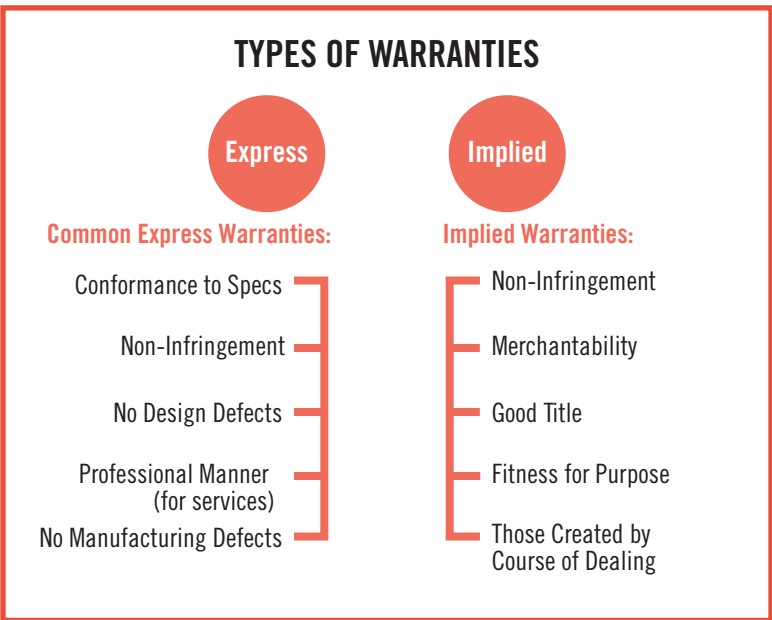
IV. Franchise Agreement.

- A. Overview.** Supplier (called the franchisor) contracts with a franchisee, who (i) purchases product from Supplier for re-sale in the contractually-prescribed territory and/or (ii) operates a local business that, to the outside world, is indistinguishable from Supplier's locations. This model is a hybrid of a distributorship that involves additional statutorily-prescribed factors (which usually include the payment of a franchise fee by the franchisee to the Supplier and a heavy reliance by the franchisee on the trademarks of the Supplier). This model requires the Supplier to furnish franchise disclosures akin to securities offering circulars, and registration in certain states.

- B. Compensation.** Franchisee resells the product at a markup, with such profit being the franchisee's only compensation.
- C. Credit Risk.** Franchisee bears the credit risk as to the ultimate customer. Supplier bears the credit risk as to the franchisee.
- D. Control.** Supplier's control of the sales activities (including pricing) is limited by antitrust and other principles. The franchisee maintains the relationship with the ultimate customer, although, as a practical matter, the goodwill generated by the franchisee's activities accrues primarily to Supplier. Supplier must also exercise quality control over the franchisee's operations.
- E. Termination.** The termination or non-renewal of a franchise is heavily regulated, making termination difficult in many states unless the Supplier has good cause.

V. License Agreement.

- A. Overview.** Supplier (called the licensor) contracts with a licensee, who licenses Supplier's intellectual property and technology in order to manufacture and sell the product.
- B. Compensation.** Licensee receives the revenue generated from the sales of the licensed product, while Supplier receives a royalty, typically based on the revenue generated from the licensee's sales of licensed products.
- C. Credit Risk.** The licensee bears the credit risk as to the ultimate customer. The Supplier bears the credit risk as to the licensee.
- D. Control.** Supplier typically has very little control over the licensee's sales activities and maintains no relationship with the ultimate customer.
- E. Termination.** Unless the licensing relationship also satisfies the elements of a franchise, then issues surrounding term/termination are purely a matter of contract.



WARRANTIES

Rich Casper and Kate Wegrzyn

Warranties are of two types: express warranties and implied warranties.

I. Implied Warranties

Sections 2-314 and 2-315 of the U.C.C. impose on sellers broad implied warranties of merchantability and fitness for particular purpose, and provide for the possibility of other, implied warranties arising from course of dealing or usage of trade (in addition to the warranties of title and freedom from infringement found in U.C.C. § 2-312).

- A. Implied Warranty of Merchantability.** There is an implied warranty of merchantability in each sale of goods contract, unless excluded or modified. In order to be merchantable, goods must at least:
- Pass without objection in the trade under the contract description;
 - Be of fair average quality within the description (for fungible goods);
 - Be fit for the ordinary purposes for which such goods are used;
 - Run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved;
 - Be adequately contained, packaged, and labeled as the agreement may require; and
 - Conform to the promise or affirmations of fact made on the container or label, if any. U.C.C. § 2-314(2).
- B. Implied Warranty of Fitness for a Particular Purpose.** Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is, unless excluded or modified under U.C.C. § 2-316, an implied warranty that the goods shall be fit for such purpose. U.C.C. § 2-315.
- C. Course of Dealing or Usage of Trade.** Other implied warranties may arise from course of dealing or usage of trade (unless excluded or modified). U.C.C. § 2-314(3).
- D. Disclaimer of Implied Warranties.** As adopted in many states, the U.C.C. permits the implied warranties as to product quality to be disclaimed. The primary requirements for an effective disclaimer are: (1) notice of the disclaimer before purchase, and (2) use of **CONSPICUOUS** type. For the disclaimer of the warranty of merchantability, the disclaimer must also mention merchantability to be sufficient. A phrase that the goods are being sold "**AS IS**" is also sufficient to disclaim implied warranties. U.C.C. § 2-316.

II. Express Warranties

Express warranties are created by (a) any affirmation of fact or promise made by the seller to the buyer which relates to the goods, (b) any description of the goods, and (c) any sample or model, in each case which is made part of the basis of the bargain. It is not necessary that the seller use formal words such as "warrant" or "guarantee" or that the seller have a specific intention to make a warranty. U.C.C. § 2-313.

III. Warranty Remedies

- A. U.C.C. Remedies.** The “warrantor” (the person giving the warranty) is responsible to the buyer for all losses that can be shown to have resulted from the breach (see U.C.C. §§ 2-714 and 2-715).
- B. Limitation on Remedies.** Remedies can be limited, but
1. Damages for personal injury caused by a consumer product cannot be limited (U.C.C. § 2-719(3)),
 2. The remaining remedy must fulfill its “essential purpose”, which is generally considered to mean that the buyer must get something commensurate with the product it bought (U.C.C. § 2-719(2)), and
 3. The disclaimer must be **CONSPICUOUS** and carefully drafted.
- C. Sole and Exclusive Remedies.** Warranty remedies in supply agreements are typically limited to repair or replacement of the non-conforming products or reimbursement of the purchase price paid by the buyer for the non-conforming products. From the Seller’s perspective, the foregoing remedies should typically be expressly provided to be the sole and exclusive remedies available to the buyer for a breach of the warranties set forth in the supply agreement. U.C.C. § 2-719(1)(b).

REMEDIES

Warranty remedies are typically limited to



Repair
Repair of
Defective
Product



Replace
Replacement
of Defective
Product



Refund
Refund of
Defective
Product

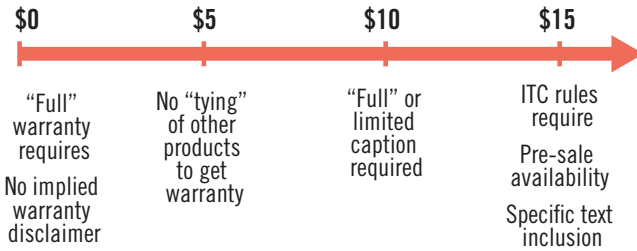
IV. Consumer Warranties

There are additional warranty laws and regulations in place to protect consumers when a warranty is given. The below is a brief overview of such laws and regulations:

- A. Federal Law Regulating Written Consumer Warranties (15 U.S.C. § 2301 (2018) et seq., the “Magnuson-Moss Warranty Act”).**
1. The statute applies only to **written warranties** and only when the products warranted are purchased for personal, family or household use. Sellers are not required to furnish written warranties.
 2. Provisions affecting warranties on **all products**: If the warrantor designates a warranty as “full”, the warranty must include certain minimum protections. Implied warranties may not be entirely disclaimed; at most, they may be limited to the duration of the written, express warranty.
 3. Additional provision affecting warranties on **products costing more than \$5**: the warrantor may not require the consumer, in order to get warranty service, to pay for anything identified by a brand name.
 4. Additional provision affecting warranties on **products costing more than \$10**: the warranty caption must include either the word “full” or the word “limited.”
 5. The statute may be enforced by the Federal Trade Commission (or the U.S. Department of Justice), state attorneys general and consumers (including class actions), and permits a court to award attorneys’ fees to a successful plaintiff. Remedies are damages and injunctions.

- B. FTC Rules Regulating Written Consumer Warranties** (16 C.F.R. Parts 701, 702 and 703): These rules apply only to warranties on **products costing more than \$15**. Disclosures required include: specific wording, and additional specific wording, if implied warranties are disclaimed or damages are limited; both warrantors and retail sellers must make the full warranty text **available pre-sale**, through the use of one or more specified means. Those rules have the **force of law**; and violations may lead to FTC fines, mandated consumer protection and/or injunctions. Consumers may not enforce them.

CONSUMER PRODUCT WARRANTY THRESHOLDS



C. State Statutes.

There is a haphazard body of state legislation/regulations of consumer warranties on specific products (see, e.g., Wis. Stat. § 100.205, as to motor vehicle rustproofing warranties). Further, California has adopted a generally applicable statute (called the “Song-Beverly Consumer Warranty Act”, Cal. Civ. Code § 1790 et seq.), notably adding that “warranty registration” cards, and even the use of that phrase, are prohibited. Most state “little FTC” laws permit consumers to make claims under the principles embodied in the FTC Magnuson-Moss rules.

D. General Federal Anti-Deception Law.

1. The Federal Trade Commission Act (15 U.S.C. § § 41-58) prohibits “unfair or deceptive acts or practices” generally; many states have similar laws.
2. On the subject of consumer warranty advertising, the FTC has adopted “guidelines” (16 C.F.R. Part 239) instructing:
 - a. any mention of a written warranty should include reference to the availability of the full warranty text, pre-sale, at the place of sale, and
 - b. if the word “lifetime” or “life” is used, an indication of what life is referred to should be included.
3. The guidelines are not enforceable by anyone as such; but failure to heed them can lead to FTC actions for injunctions against conduct that it considers unfair or deceptive. (State “little FTC” laws may be enforced by state attorneys general, and in some states directly by consumers.)

FOOD AND BEVERAGE PRODUCT RECALLS AND MARKET WITHDRAWALS

Nate Beaver and Nick Johnson

A company that manufactures, imports, distributes, stores, and/or sells food or beverages may become aware, whether through its own testing, customer complaints, reports of injuries or incidents, or otherwise, that some of its products are adulterated, contaminated, or misbranded, do not meet quality standards, or otherwise pose a risk of personal injury or illness.

In these circumstances, the company must determine what recall, market withdrawal, notification or other corrective actions (collectively referred to herein as a “**recall**”), if any, it must take to address the risk, protect the public and lessen its exposure to claims for compensatory and punitive damages arising from the product defect.

When a recall situation arises, consequential decisions must often be made quickly. This is not a time to act in an ad hoc manner. Therefore, it is critical to have a **Recall Plan** in place to guide actions at all levels of the company. This article outlines the regulatory context in which food recalls are made, and then describes the basics of a Recall Plan.

I. Who Regulates What in Food and Beverage?

Two federal agencies – the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) – are primarily responsible for regulating food and beverages at the federal level. FDA and USDA jurisdiction is both overlapping and complicated (perhaps bordering on arbitrary, even to the initiated). Below, we have provided a basic background overview of FDA and USDA oversight. The good news is that, as described further below, the recall and market withdrawal process followed by the two agencies is quite similar.

POULTRY

USDA is responsible for poultry. Under the Poultry Products Inspection Act (PPIA), poultry is defined as any domesticated bird. This includes domesticated chickens, turkeys, ducks, geese, and guineas. USDA also inspects ratites and squab, including emus. These birds are exempt from FDA’s Food, Drug and Cosmetic Act (FDCA) to the extent they are covered by the PPIA. Nonspecified birds, such as wild turkeys, wild ducks, and wild geese, are under FDA jurisdiction.

MEAT

USDA is responsible for regulating cattle, sheep, swine, goats, horses, mules, and other equines, along with their carcasses and parts. These meats are exempt from the FDCA to the extent they are covered by the Federal Meat Inspection Act (FMIA). Nonspecified red meats, such as bison, rabbits, game animals, zoo animals, and all members of the deer family, including elk and moose, are under FDA jurisdiction.

SEAFOOD

Seafood generally falls under FDA oversight. However, USDA oversees all wild-caught and farm-raised Siluriformes fish (like catfish) that are harvested and sold for human food in the United States. This includes Siluriformes fish and fish products that are imported into the United States.

EGGS

Shell eggs of domestic chickens, turkeys, ducks, geese, or guinea are subject to FDA jurisdiction. FDA regulates egg processing plants, such as plants that wash, sort, and pack eggs. Egg products, such as dried, frozen, or liquid eggs, are under USDA jurisdiction. USDA regulates egg product processing plants, such as plants that break and pasteurize eggs. FDA is responsible for products not included in USDA's definition of "egg products," as well as establishments not covered by USDA. Examples include restaurants, bakeries, and cake mix plants.

PRODUCTS CONTAINING MEAT AND POULTRY

For products containing poultry, products with less than 2% cooked poultry meat and less than 10% cooked poultry skins, giblets, fat, and poultry meat (limited to less than 2%) in any combination are regulated by FDA. Those with 2% or more cooked poultry and more than 10% cooked poultry skins, giblets, fat, and poultry meat in any combination are regulated by USDA.

For products containing other meats, products with less than 3% raw meat, less than 2% cooked meat or other portions of the carcass, or less than 30% fat, tallow, or meat extract, alone or in combination, are under FDA jurisdiction. Those with more than 3% raw meat, 2% or more cooked meat or other portions of the carcass, or 30% or more fat, tallow, or meat extract, alone or in combination, are under USDA jurisdiction.

OPEN-FACED/CLOSED-FACED SANDWICHES

FDA regulates closed-faced sandwiches, e.g., any meat between two buns or bread, while USDA regulates open-faced sandwiches.

LABELING/ADVERTISING

The FDA and USDA each is responsible for the labeling of products they regulate, as well as having authority with respect to advertising of such products. Similarly, the Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau has responsibility and authority for alcoholic beverage products. The Federal Trade Commission (FTC) maintains a broader authority, encompassing labeling and advertising of essentially all products, under its mandate to prevent false and deceptive acts or practices.

The overlap between the jurisdictions of the FTC and the FDA/USDA is managed by the FTC's cession of primary authority for food and beverage product labeling to the agency having the more specific jurisdiction, and the latter agencies' acknowledgement of the FTC's primacy as to the advertising of such products. In practice, the FTC also generally defers to the more specific agencies' expertise when they have issued regulations or guidance on conceptual issues within the scope of the agencies' jurisdictions.

II. FDA Recall Authority

FDA has the authority to order a mandatory recall when the agency determines there is a reasonable probability that a food is adulterated under Section § 402 of the FDCA or misbranded under § 403(w), and that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals. FDA must first give the responsible party an opportunity to conduct a voluntary recall. If the responsible party refuses to do so and, if the FDA commissioner issues a recall order, then FDA must first give the responsible party an opportunity for an informal hearing.

III. USDA Recall Authority

USDA does not have mandatory recall authority. However, in practice, if a regulated entity chooses to not initiate a voluntary recall as recommended by USDA, the agency is authorized to seize and detain the product at issue.

When a USDA-regulated “official establishment” becomes aware that an adulterated or misbranded meat or poultry product received by or originating from the establishment has entered commerce, USDA requires the establishment to notify the USDA-Food Safety & Inspection Service (FSIS) District Office of the incident within 24 hours. As part of the notification, USDA requires the establishment to provide the USDA-FSIS District Office with the type, amount, origin, and destination of the adulterated or misbranded product.

Product is considered to be in commerce if it is out of the producing establishment’s direct control and is in distribution (e.g., in a warehouse, distribution center, retail facility, restaurant, or other institution).

Product is considered to be under an establishment’s direct control if it is: (1) at the establishment; (2) located on the premises owned by the producing establishment; (3) at a sister establishment owned by the same corporation when no portion of the lot has been released for sale or use; (4) at a warehouse owned by the establishment or corporation; (5) on a truck or other conveyance owned or operated by the establishment or corporation; or (6) offsite under company control (e.g., under seal) or FSIS control (FSIS seal accompanied by FSIS Form 7350-1).

USDA interprets the 24-hour period requirement to begin when an official establishment has reason to believe that a product in commerce is adulterated or misbranded under the FMIA or the PPIA. For example, beef would be considered adulterated if the beef contains E. coli O157:H7. Once you learn that the beef has been contaminated, USDA expects you to notify the agency of the incident. When an official establishment notifies USDA of a misbranding or adulteration incident, USDA policy requires the agency to evaluate the report of the adulterated or misbranded product in commerce to determine where a recall or another action is needed.



IV. Recall Considerations

Even though FDA has mandatory recall authority, its policy has been to encourage manufacturers to conduct voluntary recalls or market withdrawals and, as a result, its recall authority has been used sparingly. This policy meshes with USDA's approach to recalls. Because product may become contaminated before your company receives it, during storage, processing, distribution, or off-premises warehousing, your company may be in a position to decide whether to recall the product or issue a market withdrawal and to what level of distribution (wholesale and/or retail) the recall or market withdrawal should extend.

Under what circumstances should the company decide to conduct a recall? No one can answer that question other than the company, its advisors, and legal counsel. Decisions must be made on a case-by-case basis, depending on the factual evidence. Conditions that may trigger a recall may include, but are not limited to, the presence of pathogenic microorganisms, microbial toxins, undeclared allergens, pesticide residues, unapproved additives, metal contamination, inadequate processing, glass contamination, substandard quality, and certain cGMP violations.

In determining whether to conduct a recall, one threshold consideration is whether a defective product has left your company's control. If your company is certain that it has not, then the company is probably not in a recall situation – although your company may still have an obligation to notify the FDA of a “reportable food” pursuant to the Reportable Food Registry. A reportable food is generally one that would be considered a Class I Recall (i.e., presents a serious risk to human health or safety). The company is required to notify FDA within 24 hours of determining that an article is a reportable food.

Another threshold consideration is whether the product in question is an end product (produced by your company) or a raw material used as an input (produced by another company). If the latter, your company may need to rely on the company that produced the product for key information about the recall process (for example, lot code/SKU/batch information, or how to dispose of unused product).

Regardless of the circumstances, the company should make a recall on a voluntary basis if the product in question poses a risk or threat to human health.

A difficult decision arises when the harm is not imminent, or is only a remote possibility, and the present circumstances do not appear to be severe, or even serious. Even in this case, your company may wish to make a voluntary recall or market withdrawal in order to meet customer expectations (or otherwise, depending on your company's individual risk tolerance).

Ultimately, the decision should be made by the most senior company official, based on evidence and advice provided by the company's recall team. High stakes, such as potential criminal liability, product liability, bad press, and substantial financial loss, add to the difficulty of the recall decision.

Therefore, having a recall plan in place before the company is presented with an emergent recall situation is critical.

Adhering to the guidelines in the recall plan will help create an efficient, organized, and professional response to the recall.

V. Recall Organization

A. Recall Objectives

Set up basic objectives for the recall. These should be tailored to your specific company objectives, but in general, your recall plan should focus on achieving the following:

- Identify the location of the product and its depth in the supply chain (i.e., has it reached the consumer level? Or is it still in warehouses?)
- Communicate with customers to ensure that the affected product will be segregated/quarantined to facilitate recall or market withdrawal.
- Gather and disseminate accurate information concerning the nature of the recall (i.e., whether it involves a minor labeling infraction or is likely to cause adverse health consequences).

B. Recall Team

Set up a Recall Team, which should be led by a Recall Director. The Recall Director should be a person who is in a position to direct the recall efforts and make critical decisions. Each company should assemble its own Recall Team with input from the Recall Director, and may include members of the following business units:

- Technical personnel (to identify and evaluate problems, including potential health effects);
- Operations personnel (to identify necessary records);
- Distribution personnel (to identify/locate affected product);
- Financial personnel (to track costs and reimbursements);
- Public relations (communication with public officials, news media, customers, and consumers);
- Legal representatives; and
- Marketing and sales personnel (to communicate with affected customers).

C. Division Coordination

If the company has separate divisions, each company division office should designate a Division Recall Coordinator. The Recall Director should notify the Division Recall Coordinators about recalls via prespecified electronic and/or written communications. Each Division Recall Coordinator then takes responsibility for communicating and coordinating the recall according to division functions.

For example, if the company has a sales division, then the Sales Division Recall Coordinator would be responsible for coordinating and communicating with retail outlets. Similarly, the company's Distribution Division Recall Coordinator would be responsible for coordinating and communicating with warehouses and transport organizations within the company's network. Obviously, some flexibility may be required based on your company's individual functions and business units.

However, it is important to remember that although recall coordination necessarily involves all business units, recall decision-making must remain centralized at the executive level. Division staff should not unilaterally initiate a product recall.

VI. Determining the Need for a Recall

The company may learn about potential issues from customers, suppliers, regulatory agencies, news media, or other means. All reports of possible product defects or serious illness/injury believed to be associated with a company-distributed product should be promptly forwarded to the Recall Director for further investigation.

A hazard assessment should be performed and should consider the degree of seriousness of the situation, the impact to the consumer, the likelihood of the occurrence of the event, and the potential consequences if the event were to occur. If necessary, the product should be retrieved for inspection.

If an illness, injury, death, or product tampering incident is identified or alleged, or if actual or potential adulteration or misbranding is identified, suppliers, distributors, and customers (as appropriate) should be notified and traceability programs initiated immediately.

The company should involve the Recall Team when determining the classification of the recall. FDA assigns numerical indicators (Class I, II, or III) to recall situations based on the degree of consumer hazard associated with the product being recalled:

- Class I Recalls involve products that could cause serious health problems or death (for example, pathogen-contaminated foods, botulinum toxin, undeclared allergens, or dangerous foreign materials).
- Class II Recalls involve products that might cause a temporary health problem, or pose a slight threat of a serious nature (for example, undeclared source of allergen or nonsharp foreign materials).
- Class III Recalls involve products that are unlikely to cause any adverse health effects, but that violate FDA labeling or manufacturing laws.



VII. Recall Communications

A. Who Should Be Notified?

Before a recall, it is best to establish contacts that can assist the company through the process or a related crisis event. Third-party laboratories, industry experts (e.g., microbiologists or other food safety experts), public relations firms, etc., can be excellent resources. If applicable, the Recall Team should designate somebody to contact insurance carriers as well.

- At a business level: The Recall Director should issue the recall or withdrawal notification to divisions, distributors, retail stores, suppliers, and other company facilities, as appropriate. If initial contact is via phone, follow-up information should be sent by email with a subject heading appropriate to communicate the urgency of the situation.
- At the consumer level: When the recalled product has been sold to consumers, consumers should be notified. The following useful, practical information should be provided to assist consumers in identifying the recalled product:
 - Product description (i.e., product name, brand, type, package size)
 - Identification code (i.e., UPC, sell by/use by date, expiration date, lot code)
 - Responsible party contact information. This should be centralized to ensure that questions/concerns are addressed and triaged as appropriate.
 - Reason for the recall

At the outset, the Recall Team, along with company management and counsel, should determine whether FDA will be notified (where the food is otherwise not subject to the Reportable Food Registry). Generally speaking, it is strongly recommended to notify FDA when a recall is undertaken. However, recall notification is not a legal requirement and there may be instances when FDA notification is determined to be unnecessary. *Be prepared to justify, including with documentation, the reason why FDA was not notified in the event of a later inspection where the recall is identified by FDA.*



B. Public Communications

In the event of a Class I Recall (or other serious recall situation), the Recall Team should develop a list of talking points, including known facts and corrective actions. Press releases, information scripts, website postings, social media messages, communications to company employees, shareholders, and other stakeholders should be coordinated to ensure consistency and timely release of pertinent details. Media relations should continue to monitor news media and social media channels during and after the recall.

Only individuals approved by senior management should talk to the media. Company employees should be instructed not to talk to any media representative and immediately refer all calls to the designated media representative.

VIII. Effectiveness Checks/Product Disposition

Effectiveness checks should be used to demonstrate that the recall was successful in removing product from the distribution system, as well as the retail shelf. It also provides documentary evidence that product disposition instructions were followed.

The Recall Director should be responsible for coordinating recall effectiveness checks at all affected locations to verify receipt of the product recall notice. These checks can be conducted electronically, by phone, or by physical visit. Effectiveness checks should verify receipt of the recall notice and that the receiving party took the actions directed in the recall notification. Effectiveness Check Response Forms should be returned from stores, warehouses, and/or distribution centers, etc., within 24 hours of receipt of a Class I notification and within 48 hours of receipt for all other recall situations.

All affected stores, warehouses, distribution centers, etc., should be required to complete Effectiveness Check Response Forms even if no product is located at that location. Any warehouse or distribution center aware of having shipped product to another location should contact the consignee regarding the recall. Copies of all recall communications, along with the completed Effectiveness Check Forms, should be forwarded to the Recall Director.

Expect regulatory agencies to visit facilities to audit the recall documentation. Officials will verify effectiveness check documentation, including the number of stores contacted and the amount of product removed, and may check the store or facility to ensure that recalled product does not remain in the system.

The Recall Team and/or regulatory agency will determine the appropriate product disposition. Ideally, a centralized location should be established to collect and consolidate all returned stocks of the recalled product. The recalled product should be segregated and properly labeled to prevent return into distribution channels. All affected locations should retain documentation of disposal, including date/time, method of disposal, amount of product disposed of, and witnessing supervisor's signature.

IX. Recall Termination/Evaluation

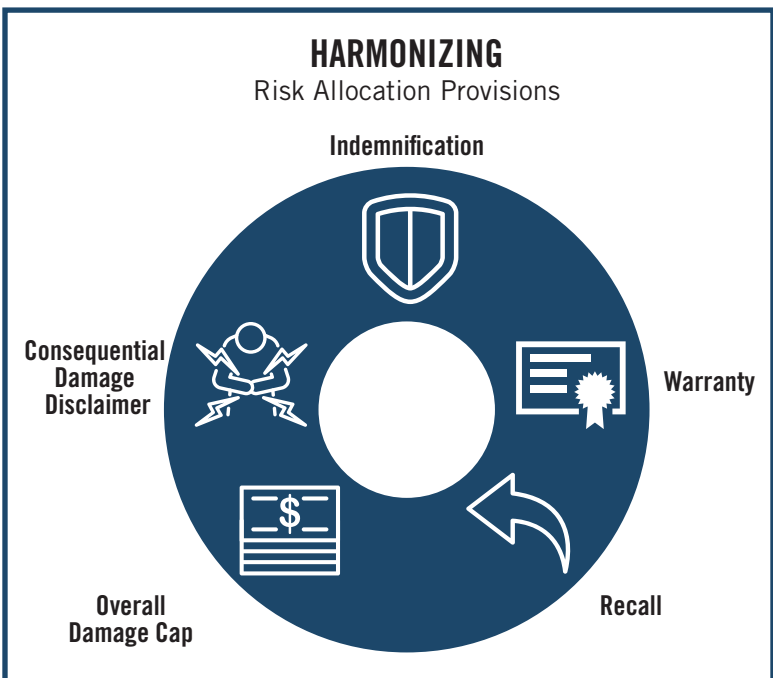
The Recall Director should be responsible for determining when a recall is to be closed (in conjunction with the regulatory agency, as applicable). Once the company believes that all affected product has been removed from distribution and/or retail, termination of the recall may be requested from the appropriate regulatory agency. The Recall Director may be required to submit written evidence demonstrating the effectiveness of the recall efforts, the status of the recovery efforts, and documentation detailing the disposition of the recalled product. The recall will not be officially terminated until the regulatory agency affirms it is closed.

The Recall Team should complete an analysis to determine the effectiveness of the recall efforts and to develop a corrective action plan to prevent recurrence. The Recall Director, with assistance from the Recall Team, should evaluate the strategy employed during the recall. The Recall Director should also prepare a final recall report, including information such as:

- The reason for the recall;
- The depth of the recall;
- The amount of recalled product accounted for;
- Disposition of the recalled product;
- Recall effectiveness (number of checks; percent compliance);
- Corrective actions taken to prevent recurrence;
- Number of consumer illnesses or injuries reported; and
- The total cost of the recall.

X. Recall Information Sources

- 21 C.F.R. Part 7
- Guidance for Industry: Product Recalls, Including Removals and Corrections
- FDA Draft Guidance: Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C



INDEMNIFICATION

Kate Wegrzyn

I. What is Indemnification?

According to Black's Law Dictionary (10th ed. 2014), indemnity is a "duty to make good any loss, damage, or liability incurred by another." At its core, an indemnification is a promise to reimburse a person for a loss incurred by that person. Often, the obligation to indemnify is limited to third party claims. Further, there is typically a "defend" component to the indemnity that requires the indemnifying party to take over the defense of the claim on behalf of the indemnified party. The following are a few of the common subjects of indemnities found in supply agreements:

- Negligence and willful misconduct.
- IP infringement.
- Failure to comply with law.
- Personal injury and tangible property damage.

II. Consistency with Limitation of Liability Provisions

One must always be mindful of the interplay of the risk allocation provisions in a contract. For example, if the agreement contains a broad indemnity stating the indemnifying party will indemnify the indemnified party against all losses resulting from specified causes, and also includes a consequential damage disclaimer providing that neither party will be responsible to the other party for consequential damages, the agreement has an inherent inconsistency, which is not good for either side because neither can depend on an outcome (that is, the indemnified party does not know if its reputational or other consequential losses will be indemnified, for example, and the indemnifying party does not know if it is responsible to indemnify for reputational or other consequential losses). As another example, third party claims are typically classifiable as a consequential damage. If an agreement contains both an indemnity for third party claims and a consequential damage disclaimer, an internal conflict exists in the agreement, potentially leaving it to a judge or jury to determine what outcome was intended by the parties. As a result, it is important to ensure that contracts expressly address how indemnification clauses and damage disclaimers interact with one another.

III. Indemnification vs. Warranty

How is an indemnification different from a warranty? A warranty and an indemnity are two different tools serving two different purposes.

- A.** First, an indemnity is usually broader than a warranty. A warranty typically only covers certain contractually prescribed (or implied by law) defects in a product, whereas an indemnity frequently covers a much more expansive array of concerns, like the negligence or willful misconduct of the indemnifying party that harms a third party who then brings a claim against the indemnified party (whether or not that negligence or willful misconduct relates to a product or a defect in a product).
- B.** Second, an indemnity typically includes an express requirement to defend the indemnified party against the claim incurred (such as, "Seller hereby agrees to indemnify, *defend*, and hold harmless Buyer

from and against...”), and expressly provides for the indemnifying party to cover attorneys’ fees. Neither of these protections are usually afforded by a warranty.

- C. Third, warranty remedies are typically limited to repair or replacement of the affected product at issue, or reimbursement of the purchase price paid by the buyer for the affected product. In contrast, indemnification obligations are often unlimited and expressly carved out from any overall damage caps in the contract.

INDEMNIFICATION VS. WARRANTY

Breadth	Typically broader than warranty	Often limited to the product
Defense Costs	Typically expressly covered	Not typically covered
Remedy	Often carved out of liability caps and disclaimers	Typically limited to repair, replace, or refund
Third Party Claims	Typically expressly covered	Not typically covered

IV. Indemnification Procedures

In addition to paying careful attention to the scope of the indemnification obligations themselves, it is also important to ensure that indemnification procedures are addressed:

- A. **Notice of the Claim.** First, the indemnifying party will want to ensure that, when a claim is made against the indemnified party for which it will seek indemnification, the indemnified party provides prompt written notice to the indemnifying party of the claim.
- B. **Control of the Defense.** Second, the indemnifying party should include a provision that gives it the right to have sole and exclusive control of the defense of the claim. The indemnifying party likely does not want to be in a position of having to reimburse the indemnified party for its defense costs and the cost of the settlement or judicial award; the indemnifying party typically would rather be in charge of the defense so that it can work to resolve the claim as quickly and cost-effectively as possible. The indemnified party may want to include a right to participate in the defense of the claim, at its own cost and subject to the right of the indemnifying party to control the defense.
- C. **Requirement to Cooperate.** Often, the indemnified party will have access to key documents or witnesses that the indemnifying party needs for the defense of the claim. As such, it is important to include an express obligation on the indemnified party to cooperate fully with the indemnifying party’s defense of the claim.
- D. **Settlement Rights.** The indemnifying party wants the broadest possible settlement rights, while the indemnified party often pushes for the narrowest. A compromise is often reached with the indemnifying party having the right to settle without the indemnified party’s consent if the settlement imposes only a monetary obligation to be paid by the indemnifying party (that is, no fault is ascribed to the indemnified party and no rights of the indemnified party are infringed).

CONSEQUENTIAL DAMAGE DISCLAIMERS AND LIQUIDATED DAMAGES

Kate Wegrzyn

I. What are Consequential Damages?

Consequential damages are “[l]osses that do not flow directly and immediately from an injurious act but that result indirectly from the act.” *Damages*, *Black’s Law Dictionary* (10th ed. 2014).

Let’s take a straightforward example: If you get sick from eating food with microbial contamination (e.g., botulism), your hospital bills are clearly direct damages. On the other hand, if you are out of work for six months recovering from the illness, your lost wages during that time are consequential damages. Note that, although the damages are consequential, in terms of the financial impact on you, they are no less real than the direct damages. The same is true in a commercial scenario; consequential damages are just as real and destructive as direct damages.

CONSEQUENTIAL DAMAGE DISCLAIMER Easy Example



II. Examples of Consequential Damages

Below are common examples of consequential damages in a commercial context:

- Loss of anticipated profits;
- Loss of use of goods or services to be provided;
- Loss of business;
- Cost of unsuccessful attempts to repair defective goods;
- Loss of goodwill;
- Losses resulting from interruption of buyer’s production process;
- Loss of reputation; and
- Loss of sales contracts because of delayed products.

III. Disclaimers of Consequential Damages

- A. **Permissibility of Limiting Consequential Damages.** Consequential damages may be limited or excluded in a contract unless the limitation or exclusion is unconscionable. (Limitation of consequential damages for injury to the person in the case of consumer goods is prima facie unconscionable, but limitation of damages where the loss is commercial is not.) U.C.C. § 2-719(3).

- B. When to Limit Consequential Damages.** In theory, the definition of consequential damages is not that complicated, but in application, the results become muddled. Commercial contracts often include a consequential damage disclaimer, but one reason to resist such a disclaimer may simply be to avoid contentious and expensive litigation over whether a party's damages were direct or consequential in nature. Generally speaking, the buyer of a product or recipient of a service will want to resist a disclaimer (even a mutual disclaimer) of consequential damages, because such a disclaimer is much more likely to benefit the seller or service provider than the buyer or service recipient. For example, typically, the buyer's primary or only obligation under a supply agreement is to pay for the product, the failure to do which does not carry with it as much risk of consequential damages as the sale of a product creates for the seller. On the other hand, the seller of a product could be subject to a host of consequential damages in the event it fails to timely deliver the products or delivers defective products and, as such, the seller will want to push for a consequential damage disclaimer.
- C. Personal Injury and Property Damages from Warranty Breaches.** Article 2 of the U.C.C. provides that personal injury or property damage proximately resulting from any breach of warranty is a consequential damage. U.C.C. § 2-715(2)(b). As such, if a contract includes a consequential damage disclaimer, a buyer's warranty remedies will not help the buyer in the case where the product is defective and causes property damage (it should be noted that a warranty remedy provision may also provide for sole and exclusive remedies of repair/replace/refund; in such case the warranty remedies will not protect the buyer for such property damage claims, even in the absence of a consequential damage disclaimer).
- D. Drafting Notes.** The 1976 Seventh Circuit decision in *Berwind Corp. v. Litton Indus., Inc.*, 532 F.2d 1, has greatly influenced how practitioners draft liability limitations in contracts for the sale of goods, through its suggestions that practitioners should:
1. Separate liability limitations from warranties,
 2. Make liability limitations **CONSPICUOUS**, and
 3. Explicitly mention that liability limitations apply to "torts" and/or "negligence."



IV. Carve outs from the Consequential Damage Disclaimer

In most arm's-length commercial agreements between sophisticated parties, the parties will agree to include a consequential damage disclaimer that is subject to certain carve-outs that permit a party, in certain situations, to recover consequential damages from the other party. The most common carve-outs from a consequential damage disclaimer are as follows:

- A. Third Party Indemnification Claims.** Claims brought by third parties for which a party is entitled to be indemnified should be carved out from consequential damage disclaimers. If an indemnifying party commits an act for which it has provided an indemnity under the agreement (for example, an indemnity for claims arising from that party's negligent acts or omissions) and that act injures a third party who then sues the indemnified party, the indemnified party will expect to be held harmless from that suit. However, a claim by a third party (and the defense of such claim) is likely to be classified as a consequential damage with respect to the indemnified party. As such, an indemnity could be deemed overridden by a broad consequential damage disclaimer that does not properly exclude third party claims.
- B. First Party Negligence and Misconduct.** In addition to third-party indemnification claims (which may, depending on the indemnity provision, include third-party claims resulting from a party's negligence or willful misconduct), where bargaining power permits, the buyer should push for a separate carve-out from the consequential damage disclaimer for "first-party" negligence or willful misconduct. That is, if a party is negligent or acts with willful misconduct, and the other contractual party is injured as a result, the injured party should be entitled to recover all damages resulting from such negligence or willful misconduct, regardless of whether those damages are direct or consequential. As explained above, a consequential damage is still a real damage that a party must prove it has suffered. From the perspective of the buyer, there is no reason the seller should be excused from liability for such damages arising from that party's negligence or willful misconduct simply because the damages are consequential. It should be noted that, in states that have adopted the Economic Loss Doctrine, this carve-out will not be sufficient to preserve a claim for economic losses resulting from the failure of a product, even if it was negligently designed or manufactured. To recover those types of losses in such states, the parties will need to include an indemnity for first-party negligence and willful misconduct or carve such losses out from the sole and exclusive remedy provisions of the warranty. Sellers' perspectives are, of course, often entirely different. They do not expect to bet their companies on whether they can successfully defend a claim that they negligently designed or manufactured a product sold to a single customer, so sellers typically will want a consequential damage disclaimer to cover first-party negligence claims.
- C. First Party Intellectual Property Infringement.** Where intellectual property is involved, the indemnity should include an indemnification by the seller for infringement of the intellectual property rights of a third party. If so included as an indemnity, these third party claims will already be carved out from the consequential damage disclaimer by virtue of the first carve-out listed above. However, where buyer's intellectual property is involved, the buyer should also push for

a carve-out for damages incurred by the buyer as a result of an infringement by the seller of the buyer's intellectual property rights. The damages resulting from an infringement of intellectual property rights are often going to be consequential (for example, lost profits or loss of market share). As such, for a buyer to have an adequate remedy for infringement by the seller of the buyer's intellectual property rights, first party intellectual property infringement would need to be excluded from the consequential damage disclaimer.

- D. Product Recall.** If a buyer needs to conduct a product recall or other field corrective action, the buyer may incur expenses that far exceed the cost of replacing, repairing or refunding the price of the product (which would be the direct damage, and which often are the sole remedies for a warranty claim). For example, there may be fines by regulatory agencies, money spent canvassing to reach purchasers, internal costs of employees dedicating time to the recall, attorneys fees, and costs of field work, among others. Buyers should attempt to exclude such recall-related expenses and losses from the scope of any consequential damage disclaimer.
- E. Breach of Confidentiality.** The reason for carving damages arising from a breach of confidentiality out of a consequential damage disclaimer is that the bulk of damages that arise from a breach of confidentiality will, in fact, be consequential. As with intellectual property infringement claims, in order for a party to have an adequate remedy for a breach of the confidentiality provisions, damages resulting from breaches of confidentiality must be excepted from the consequential damage disclaimer.

V. Liquidated Damages

The U.C.C. permits liquidated damages, but only at an amount which is reasonable in the light of the anticipated or actual harm caused by the breach, the difficulties of proof of loss, and the inconvenience or nonfeasibility of otherwise obtaining an adequate remedy. A term fixing unreasonably large liquidated damages is void as a penalty. U.C.C. §2-718(1). In appropriate circumstances, parties may want to negotiate reasonable liquidated damage clauses to address delays in delivery, performance shortfalls, or other breaches. Such clauses can give both parties a degree of certainty with respect to the consequences of the breaches in question.



WHEN ANTITRUST LAW AND ROUTINE COMMERCIAL TRANSACTIONS INTERSECT

Rich Casper

I. What are the Relevant “Antitrust Laws”?

- A. Sherman Act § 1.** In the U.S., Section 1 of the Sherman Act (15 U.S.C. § 1) is the most fundamental of them. Its deceptively simple language prohibits “[e]very contract, combination... or conspiracy, in restraint of trade or commerce,” but the determination of the meaning of that language occupies the bulk of antitrust case law.
- B. Clayton Act § 3.** Section 3 of the Clayton Act (15 U.S.C. § 14) prohibits, in certain circumstances, exclusive dealing agreements (which may also be challenged under Section 1) and the “tying” of sales of one product to the buyer’s agreement to purchase another of the seller’s products.
- C. Robinson-Patman Act.** Section 2 of the Clayton Act (15 U.S.C. § 13), which is usually referred to as the Robinson-Patman Act (the name given to the amendatory legislation that created it), prohibits certain types of discrimination in connection with the sale of “commodities.”
- D. Federal Trade Commission Act § 5.** Section 5 of the Federal Trade Commission Act (15 U.S.C. § 45) prohibits “[un]fair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce.”
- E. State Legislation.** Various state laws address the same subjects. In many cases, the difference between the practical effects of those laws and their federal counterparts are little more than that the state laws apply to purely intra-state practices. In other cases, for example some of the “little FTC Acts”, the states create private causes of action that are not present under Section 5. In still others, e.g., MD Code Ann., Com. Law § 11-204(a) (which absolutely prohibits minimum resale price fixing), states have prohibited practices that might be legal under federal law.

II. What Specific Practices does Section 1 Regulate?

- A. Multiple Actors Required.** Section 1 only covers multi-party arrangements. It does not apply to unilateral conduct, for example a supplier’s choice not to sell to another person interested in buying. It also does not apply to arrangements between companies affiliated by ownership of equity.
- B. The Rule of Reason.** In the earliest U.S. Supreme Court decisions applying Section 1, the Court noted that the literal breadth of Section 1 would prohibit all commercial contracts, as every sale restricts other sales by limiting what can be sold to others. To avoid this absurd result, the Court interpreted Section 1 as prohibiting only “unreasonable” restrictions, with reasonableness determined by a weighing of the benefits of the restriction against the extent of its detriment. This analysis came to be known as the “rule of reason.”
- C. The Per Se Rule.** Because rule of reason analysis is fact-intensive and inherently subjective, the Court later adopted a shortcut category for commercial practices that it judged so inherently detrimental

to commerce that they could not be justified by any countervailing benefit. Such restrictions were pronounced “per se” illegal.

- D. Horizontal Restraints.** The paradigm of a per se restraint is an agreement between competitors or potential competitors (often called a “horizontal” agreement), as to prices that they charge, a category that includes customer and territorial allocations between competitors. Such agreements are frequently attacked as criminal violations of the antitrust laws.
- E. Vertical Restraints.** In contrast, restraints in agreements between suppliers and their customers (“vertical” agreements) are analyzed under the rule of reason and seldom lead to criminal prosecution.
- F. Extraordinary Remedies.** Aside from criminal penalties, violations of Section 1 can result in injunctions and civil suits by regulators and by private parties injured by prohibited conduct; in private actions, a successful plaintiff will be entitled to recover treble damages (three times the damages proven), and its attorneys’ fees.
- G. Vertical Price Fixing.** For many years, vertical price fixing agreements were considered per se illegal. That changed as a result of a series of Supreme Court decisions. However, while federal law analyzes all vertical price fixing under the rule of reason, some states may not follow the same principle in applying state antitrust laws, most notably under the Maryland statute prohibiting minimum resale price fixing agreements altogether (see citation in subdivision 1.E above).
- H. “MAP” Policies.** Minimum advertised price (generally called “MAP”) policies were developed to skirt the former per se illegality of minimum resale price fixing. They did that by (1) prohibiting only advertising of prices below an established minimum, not sales at such prices, and (2) avoiding any interactive involvement of a supplier’s customers, i.e., the supplier notifies the customers of the policy, does not ask for the customers’ agreement to it and refuses to discuss it with customers.
- I. Inferential Proof.** Almost all horizontal antitrust violations are proven by inference from the parties’ conduct (i.e., not from express agreements). Thus, an exchange of price information between competitors, followed by similar pricing by the companies involved, is an example of proof of a horizontal price fixing agreement.

COMMERCIAL TRANSACTIONS AND THE ANTITRUST LAWS

What Law Applies

	Sherman Act	Robinson-Patman Act	State Statutes	Clayton Act	FTC Act
Consumer Warranties					
Labeling					
Advertising					
Pricing					
Distribution and Supply Chain Agreements					

III. What does the Robinson-Patman Act Cover?

- A. Section 2(a).** Section 2(a) prohibits discrimination in the prices that a seller charges to its customers, in certain circumstances. It is to be stressed that, although the favored purchasers are the ones who benefit from the discrimination, the primary target of the statutory prohibition is the discriminatory seller.
- B. Difficulties in Section 2(a) Cases.** Section 2(a) cases are complicated by the number of elements of the offense, including particularly the need to prove “injury to competition”, and by the number of defenses. They are therefore difficult for a plaintiff to win, and expensive for both sides.
- C. Elements of the Offense.** The elements of a claim are actual sales (e.g., not one sale and one offer to sell) to two different purchasers, at least one of which crosses state lines, the sales must be of goods (not services or other intangibles), the goods in the two sales must be of “like grade and quality”, the sales must have been “reasonably” contemporaneous, the prices must have been different, and the price difference must have caused injury to competition, not merely injury to the disfavored purchaser (so, unless the seller’s product is a significant component of the costs of the purchasers’ businesses, e.g., where the purchasers are competing resellers, there will not likely be a violation).
- D. Defenses.** Even if all of those elements are satisfied, the price difference will not violate Section 2(a) if any of the following defenses is proved by the seller:
- The lower of the prices was provided to meet (not beat) a competitive price available to the favored purchaser,
 - The cost to the seller of making the sale to the favored purchaser was lower than the cost of selling to the disfavored purchaser, by the amount of the price difference,
 - The price difference is attributable to changes in market conditions,
 - The favored purchaser performs services relating to the resale of the goods, e.g., warehousing or warranty coverage, that the disfavored purchaser does not perform, and the value (or cost to the favored seller) is approximately the same as the price difference, or
 - The lower price was offered to the disfavored purchaser and could, as a practical matter, have been accepted by the disfavored purchaser; obviously this will usually be in the context of offering a lower price on some condition such as buying in a particular minimum volume (but note that smaller customers may not be disfavored for refusing to buy in volumes they cannot use).
- E. Section 2(c).** Section 2(c) was an amendment to the Robinson-Patman Act designed to prevent sellers from circumventing Section 2(a) by paying purchasers’ agents, including employees. The wording of the statute, however, also prohibits commercial bribery by sellers. Further, neither the elements nor the defenses applicable to Section 2(a) apply to the conduct prohibited by Section 2(c). Thus, it is almost always better for a seller to charge a lower price to a complaining customer than to agree to make payments to an agent of the customer.

- F. Discrimination in Promotional Assistance.** Sections 2(d) and (e) require that a seller offering assistance to competing resellers in connection with their resale of the seller's products do so on a "proportionately equal" basis. (This requirement applies to protect both resellers that buy directly and those that buy from intermediaries, such as distributors.) The typical arrangement addressed by this requirement is a co-op advertising program under which the seller contributes to the cost of its customers' advertising. The benefits of such a program must be equally useful, as a practical matter, to smaller resellers, although the value of using the program is expected to be in proportion to the resellers' purchase volumes. Again for Section 2(d) and (e) claims, for the most part neither the defenses to a Section 2(a) claim, nor its associated elements, apply.
- G. "Fred Meyer" Guides.** The FTC has published guidelines about how to draft and administer compliant promotional assistance programs.
- H. Exception for Sales to Federal Government.** Sales to the federal government are exempt from the Robinson-Patman Act, but not sales for resale to the federal government.
- I. Extraordinary Remedies.** As is the case in Sherman Act Section 1 cases, a successful Robinson-Patman plaintiff can recover treble damages and attorneys' fees.

IV. What does the Federal Trade Commission Act Cover?

- A. Unfair or Deceptive Acts.** As noted above, this Act prohibits the general category of "unfair or deceptive" acts or practices. It is enforced exclusively by the U.S. Federal Trade Commission (the "FTC"), though as also explained above, private causes of action for violation of state "little FTC" statutes exist in many states.
- B. FTC Rules.** Under the authority granted to the FTC, it has adopted a number of formal rules, the violation of which carry specific monetary penalties without resort to the courts. Among the broadest of those rules are those regulating written consumer warranties, "mail-order" (including internet) sales, and the sale of franchises (requiring extensive disclosures).
- C. FTC Informal Guidance.** The FTC has also provided less formal guidance on numerous topics relating to the advertising and labeling of products, including:
 - The "Green Guides", concerning environmental marketing claims,
 - Guides regarding the use of endorsements and testimonials in advertising,
 - A policy concerning representations that products are of U.S. Origin, and
 - A policy regarding substantiation of advertising claims generally.
- D. Ancillary Use of FTC Guidance.** The guidance provided by the FTC is very influential as a source of law in challenges to advertising in various contexts, including voluntary adjudication by the National Advertising Division of the Better Business Bureau, enforcement actions by other agencies having ancillary jurisdiction (e.g., the FDA and the USDA), and class actions under state statutes and common law theories.

NON-DISCLOSURE AGREEMENTS

Kate Wegrzyn and Heba Hazzaa

I. Is a Non-Disclosure Agreement (“NDA”) Necessary?

When considering entering into an NDA, the first question to ask is whether it is necessary for either party to be disclosing confidential information. If you must disclose your confidential information to another party, an NDA is a helpful tool to protect that information, but the best way to protect your confidential information is to not disclose it at all. Conversely, consider whether and how much confidential information you need to receive from the counterparty. Once you receive a party’s confidential information, if you are bound by an NDA, you have committed to protecting that information under the terms of that NDA.

II. Scope of the Definition of “Confidential Information”

When considering the scope of the definition of “Confidential Information”, you should consider the following question: “Who is disclosing Confidential Information?”

- A. Neither Party is Disclosing Confidential Information.** There is no need to execute an NDA.
- B. Only You are Disclosing Confidential Information.**
 - 1. Sign a one-way confidentiality agreement, where only the other party is agreeing to not use or disclose your confidential information.
 - 2. Define “Confidential Information” broadly, perhaps even including language that “Confidential Information” includes information “reasonably believed” by you to be confidential.
- C. Only the Other Party is Disclosing Confidential Information.**
 - 1. Define “Confidential Information” as narrowly as possible so that you can more easily avoid violating the NDA. For example, you could have the definition only pertain to information relating to some defined subject matter (like the “potential development of X product”) and further require that, for any information to be deemed to be Confidential Information, the information must be conspicuously labeled “**CONFIDENTIAL**” at the time it is disclosed to you.
 - 2. Ensure there is a carve-out to the non-use/non-disclosure obligations for legally required disclosures. As a drafting note, this should be an exception to the non-use/ non-disclosure obligations, not an exclusion from the definition of “Confidential Information.” The distinction here is that such information should still generally be treated as confidential even though its disclosure is legally required in a specific situation.

D. Both Parties are Disclosing Confidential Information.

1. Use a two-way NDA.
2. Draft the definition of “Confidential Information” with a balance of the above concepts in mind – you want to draft it narrowly enough that you do not unwittingly violate your obligations to not use or disclose the other party’s Confidential Information, but not so narrowly that your Confidential Information is not properly protected. You also want to weigh the risk of losing the ability to sell in the marketplace if the definition is too broadly crafted.

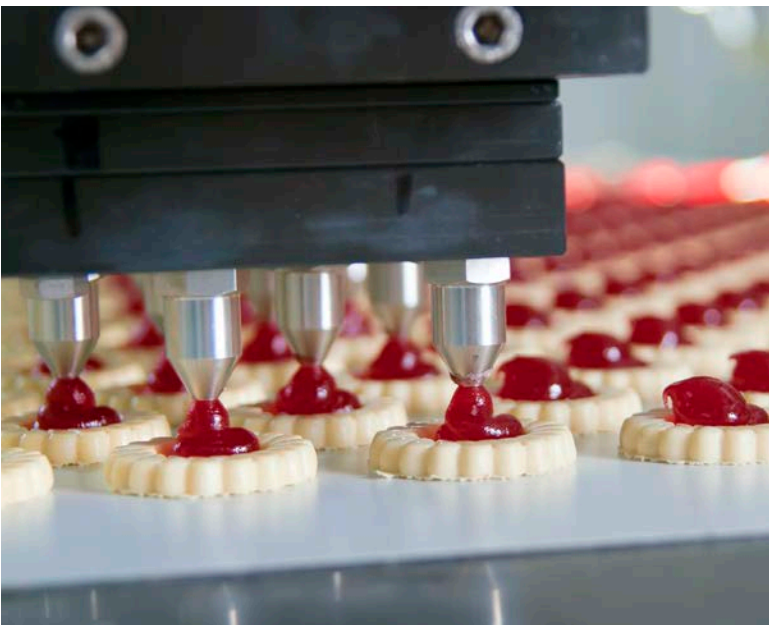
III. Exceptions to the Definition of “Confidential Information”

Ensure the necessary exceptions to what constitutes “Confidential Information” are included. The most common such exceptions are as follows:

- Information that is already in the public domain at the time it is disclosed, or that subsequently enters the public domain without breach of the NDA;
- Information that you already know at the time it is disclosed pursuant to the NDA;
- Information that a third party rightfully tells you; and
- Information that you independently develop without reference to the other party’s Confidential Information.

IV. Disclosure vs. Use

- A. A party receiving Confidential Information is typically permitted to use that Confidential Information only for the purposes identified in the NDA.
- B. The prohibition of disclosure should be absolute (that is, the receiving party should not be permitted to disclose Confidential Information for any reason), other than when legally compelled.



V. Confidentiality Period

- A. A requirement not to disclose or use the Confidential Information of another party is a restrictive covenant and, like other restrictive covenants, must aim to protect a legitimate business interest. An NDA's restrictions should be no more restrictive than reasonably necessary. To increase the likelihood that the NDA will be enforceable, consider including a time period during which a party has to maintain the confidentiality obligations under the NDA. Depending upon the circumstances, including a confidentiality period that extends for one year after the term of the applicable agreement is generally considered to be a safe length of time. However, the duration of restrictions should be carefully researched and considered on a case-by-case basis.
- B. Additionally, the confidentiality period should treat trade secrets separately from other types of Confidential Information, such that, despite any general expiration of the non-use/non-disclosure obligations under the NDA, the receiving party's obligations with respect to trade secrets will remain in effect for as long as they remain trade secrets under applicable law.

VI. Requirement to Return Confidential Information

An NDA should include a provision requiring that Confidential Information be returned (or destroyed) upon demand by the disclosing party and, in any event, upon termination of the NDA.

VII. Other Terms

On occasion, a party may try to use an NDA as a means to bind the other party to terms that are not typically found in an NDA. For example, a party may include non-competition, non-solicitation and/or non-circumvention provisions in an NDA. Or a seller entering into an NDA with a buyer may include a cross reference incorporating its standard terms of sale in order to bind the buyer to those terms for future product sales. Be on the lookout for these provisions.

VIII. Dispute Resolution Clauses in NDAs

Given the nature of NDAs, you might want to consider arbitration to avoid having to litigate the confidential aspects of your agreement in court. Arbitration is a process by which the parties select the arbitrator(s) who will resolve the dispute by a binding and enforceable decision outside of court in accordance with the parties' agreement. In your dispute resolution clause, you can agree beforehand on the number of arbitrators, their area of expertise (if necessary), the location of the hearings, and the applicable law, among other things.

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Richard H. Casper is a partner and corporate lawyer with Foley & Lardner LLP. Since 1975, he has acted as a counselor on the full spectrum of commercial matters affecting businesses, including licensing, purchasing/selling, lending, distribution/agency, and bankruptcy. His clients include manufacturers and vendors of a diverse array of goods and services, including agricultural implements, food and other consumer products, printing, software, tools, electronic equipment, and manufacturing equipment. Mr. Casper is a member of the Commercial Transactions & Business Counseling Team. He is also a member of the firm's Distribution & Franchise Practice and the Food & Beverage Industry Team.



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Nathan A. Beaver is a partner and food and drug lawyer with Foley & Lardner LLP, where his practice focuses on the representation of companies whose products and activities are regulated by the Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), U.S. Department of Agriculture (USDA) and the Federal Trade Commission (FTC). Mr. Beaver is a member of the firm's Government Solutions and FDA Practices and the co-chair of the Food & Beverage Industry Team. He is also a member of the Cannabis and Life Science Industry Teams. Mr. Beaver also has significant experience in FDA compliance and enforcement issues including product recalls and 483s, Warning Letters and Consent Decrees.



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ABOUT FOLEY & LARDNER LLP

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ABOUT THE TEAM

Foley & Lardner LLP's Commercial Transactions and Business Counseling Team supports the full spectrum of commercial matters affecting businesses, including licensing, purchasing/selling, dealer arrangements, sales agency agreements, supply chain contracts, marketing and promotion agreements, service contracts, product recalls, tolling and contract manufacturing agreements, private label agreements, consignment agreements, and logistics and transportation contracts, among others.



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