

With the Best of Intentions: Observations on the International Regulation of Franchising

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While its roots go far deeper, modern franchising as we know it today is a product of post-World War II America. That era was marked by an upsurge in interest in being one's own boss but with the greater likelihood of success, which flowed from acquiring a license to operate a business under a structure established by a larger company that had already initiated the concept. Together with the pent up demand for consumer goods and services, which had been in short supply or rationed, those developments planted the seeds for one of the most successful techniques ever devised for distribution.

Three decades would pass before laws governing this new relationship would be adopted. Most of the U.S. regulation with which we are familiar today can be traced to the legislative and political activity of the 1980s, some taking the form of pre-disclosure obligations, some the form of restrictions on franchisor conduct. Today, there is both a Federal Trade Commission Trade Regulation Rule on Franchising and legislation of one or the other of the two forms, or both, in twenty-six states.

At the dawn of franchising, none but the handful of large and relatively experienced franchisors entertained the notion of international expansion; the costs, risks, and unknowns were simply perceived as too daunting. But as the appetite for U.S. goods and services steadily increased in a world that had put the ravages of war behind it, the prevalence of cross-border franchising inexorably spread to more industries and to smaller companies. Today it is estimated that by the end of this decade half of all U.S. based franchises will be located outside the United States, with the economic and cultural sea change that has already been set in motion.

But unlike in the United States, where legal and regulatory action was accompanied by the traditional protocol of studies, debates, and the formation of interest groups on both sides of the issues, the scene beyond these shores was markedly different. With the exception of some Anglophone countries, the adoption of legislation tended to be hasty, with little forethought to the consequences. In some countries, laws were passed even though there was only a smattering of franchises. The operative syllogism sometimes seemed to be, "The United States has successful franchising. The United States has franchise laws. Ergo, if we want successful franchising, we should have

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franchise laws.” *The pace has not slackened; the laws that were a product of that era today can be found in forty jurisdictions beyond the United States.*

Now, more than thirty years after the first non-U.S. regulation of franchising appeared, it is possible to draw some conclusions and some observations about the future.

- *Too much of non-U.S. franchise regulation was adopted without adequate forethought, without credible evidence of need, and without the sort of safeguards to which we have become accustomed in developed countries.*
- *As a consequence of these and other flaws, international franchising is too often more complicated and expensive than it needs to be, even though the drafters may not have had any intention to create that result. Franchisors may be quite unaware of these complexities, drawbacks, and uncertainties until they are within the grips of the system.*
- *Much of the non-U.S. regulation of franchising is permeated with economic, social, and political concerns which have little, if anything, to do with the fundamental purpose of franchising but which have an adverse effect on franchising and a special impact on foreign franchisors entering that market.*
- *These imperfections have a deleterious effect upon prospective foreign franchisees and upon their societies and economies that could benefit from the introduction of franchising.*

The question is thus raised: Are these fundamental problems curable, or capable of being ameliorated? Or is the genie simply too far out of the bottle? This paper will address that question.

Introduction

“[Franchising] vastly increases the likelihood of success on the part of the small businessperson [I]t offers to both a degree of flexibility and security not possible under other growth systems.”¹

“It’s a smart investment now and will be long after I’m done playing football.”²

“The franchise industry could be used as a platform to reduce the economic gap between races, as well as contribute towards national integration.”³

“No two countries that both have a McDonald’s have ever fought a war against each other.”⁴

What explains this almost extravagant praise of a particular form of doing business—and from some unlikely origins? And from a wide range of sources—geographic, economic, social, political, and cultural?

To gain some perspective on franchising’s role in the economy, we must begin our inquiry in the United States. The United States is by no means characteristic of the entire world; in terms of size, demographics, and disposable income it stands apart from most other societies. But it is, after all, where franchising began, and it is the country with which it is most often associated. So it might be useful to start with a sense of where franchising fits into the American economy.

I. The Role of Franchising in the U.S. Economy

For anyone who ever consumes a meal away from home, stays in a hotel, or rents a car, it will not come as a surprise to learn that the business model is ubiquitous: there are more than 757,000 franchise establishments. What is less obvious, but economically more significant, is the number of people franchises employ (8.3 million), with

¹ Andrew Kostecka, *Foreign Franchisors in the United States*, 3 J. F. COMM. FRANCHISING 3, 3 (1983-1984).

² Press Release, Papa John’s Int’l, Inc., Peyton Manning Scores a Touchdown as Newest Papa John’s Franchisee (Oct. 26, 2012), available at <http://ir.papajohns.com/releasedetail.cfm?ReleaseID=716522>.

³ Tun Mahathir, *Franchising Can Reduce Economic Gap Between the Races*, ASIAN BROADCASTING NETWORK (Nov. 12, 2013), <http://news.abnxc.com/2013/11/mahathir-franchising-can-reduce-economic-gap-between-races/>.

⁴ Thomas L. Friedman, *Foreign Affairs Big Mac I*, N.Y. TIMES (Dec. 8, 1996), <http://www.nytimes.com/1996/12/08/opinion/foreign-affairs-big-mac-i.html>. But see THOMAS L. FRIEDMAN, *THE LEXUS AND THE OLIVE TREE* 248 (2012) (re-examining the “Golden Arches Theory of Conflict Prevention” when NATO forces bombarded the former Yugoslavia in April 1999).

economic output of almost \$802 billion.⁵ When considering those businesses that supply the goods and services necessary to support those franchised operations the numbers rise to eighteen million jobs and more than \$2 trillion in output.⁶ Far from being simply a collection of fast food restaurants and motels with low paying jobs, it is a business model which is used in more than 300 business lines and is the predominant technique for distribution in more than eighty industries, including such distinctly non-minimum wage fields of endeavor as healthcare, education, and technology.⁷

While franchising was certainly affected by the economic downturn, it has fared better than the economy at large, returning to its pre-recession employment level sooner and resuming a higher growth trajectory than the universe of all businesses. Rebounding from the effects of lower consumer spending and reduced availability of credit, it is estimated franchising showed a 4.3% increase in output in 2013.⁸

II. Advantages to the Franchisor and the Franchisee

What explains this extraordinary growth, and what explains the appeal of franchising to so many sellers of goods and services, to impel them to elect the vehicle of franchising? And, conversely, what explains the interest of so many buyers, to select the role of a franchisee rather than the role of an employee, on the one hand, or a completely independent business operator on the other?

The answer is pretty straightforward: Franchising provides a vehicle for companies to expand their distribution of goods and services in a uniform and relatively controlled fashion, by relying upon the contributions and investments of those further downstream in the distribution chain, rather than depending entirely on internally generated human and financial resources. Franchisors thus find that, while they obviously bring a smaller amount into the gross revenues of the company than if they were operating on a vertically integrated basis, their return on investment can be vastly higher, simply because the “I” in ROI (the investment) is so much lower.

While we have thus far touched upon the benefits to sellers who become franchisors, let’s drill a bit deeper and consider:

- Speed of growth. By leveraging off of the time and efforts of its franchisees, a franchisor can grow much faster without adding staff.
- Highly motivated management. Franchisees can provide a company with highly motivated managers, who will view individual units as their own.

⁵ IHS GLOBAL INSIGHT, FRANCHISE BUSINESS ECONOMIC OUTLOOK FOR 2014, at 1 (2012), available at http://www.franchise.org/uploadedFiles/Franchise_Business_Outlook_12-17-2012.pdf.

⁶ INT’L FRANCHISE ASS’N, ECONOMIC IMPACT OF FRANCHISED BUSINESS VOL. III, at 2 (2008), available at http://www.franchise.org/uploadedFiles/Prospective_Franchisee/News/EconomicImpact11.pdf.

⁷ *Id.*

⁸ IHS GLOBAL INSIGHT, *supra* note 5.

- Unit performance. Units are generally better run, as is reflected in the fact that franchised stores generally outperform company-owned stores in terms of sales volume.
- Quality control. Franchisees generally keep their units in better operational shape than unit managers and, as a part of the community, are better able to promote these units locally.
- Long-term management. The franchisor can invest in the long-term training of its franchisees, as they are unlikely to leave early or abruptly.
- Brand building. The ability to grow the organization without substantial additions to overhead will allow franchisors to grow their retail presence and their brand more quickly and effectively.
- Reduced role in day-to-day operations. As a franchisor, the franchisor's primary concern involves the franchisees' top line performance, reducing the scope of the franchisor's involvement in day-to-day management.
- Lean structure. Franchisors can grow the organization without adding significantly to overhead.
- Advertising. Franchisees will often contribute to a common advertising and promotional fund. This fund will be used to promote the brand under the direction of the franchisor.
- Limited contingent liability. The franchisor will not be signing leases, taking on financing, etc.
- Reduced vicarious liability. The liability for acts of employees (e.g., sexual harassment, EEOC violations, etc.) and for occurrences in the unit (e.g., slip-and-fall) accrues to the franchisee, not the franchisor, for the most part.
- International. International expansion becomes easier and faster and carries far less risk, since a local partner becomes involved.

And what of the franchisee? A franchise provides the buyer an opportunity to retain a substantial measure of autonomy in the operation of his (or, increasingly, her) business, while gaining the benefits of being part of a network which provides, among other resources which could not otherwise be accessed, training, advertising, research and development, and mass buying power. Let's look a bit more deeply:

- At the outset, there can be little doubt that a franchisee has a substantial advantage over an independent operator of a similar unit. Compare the two on a whole range of issues each must confront: devising an operating system vs. adapting what the franchisor has already tested; searching for a location and constructing a facility or building out space vs. following site selection processes, construction, and design used successfully in corporate and other franchised units; searching and bargaining for equipment vs. taking advantage of pre-selected equipment, frequently at a favorable price. In these and a wide array of

other matters—training, advertising, marketing, manuals—the differences are stark.

- Once the relationship has been initiated, the differences continue and may be even more marked: continuing research and development; mass purchasing power and advertising programs; pre-tested new products; the capacity to respond to changes in supply, demographics, and competitive circumstances far more readily than an independent operator can.
- Assuming the franchised chain is successful; perhaps the simplest way to envision the difference is in terms of the pre-existing recognized brand image that a prospective customer carries in his head when he contemplates patronizing a unit.

Franchising is thus simultaneously a form of distribution, a form of raising capital, and a form of organizing functions and allocating risk and reward. As a form of distribution, which is the principal focus of our inquiry, it is obviously akin to a distributorship model or a licensing model but with attributes which make it appealing to the franchisor, to the franchisee, and to an economy and a society.

III. Effects of Franchising on an Economy

What are the effects of franchising on an economy and a society? While the information is far more readily available in the United States, the effect on the global economy is by now clear. Let's consider a few of its attributes:

- Stimulation of private sector investment. Franchising is horizontal by nature. That is, the successful franchisor, having ten or twenty units in operation, typically does not then invest in a chicken processing plant or buy a fleet of trucks to deliver the chickens to his outlets. Instead, the franchisor offers those "vertical" opportunities to private suppliers and offers to other prospective operators the opportunity to replicate the system (similar units at the same level as the original, developed in a linear series from market to market). Each of those units represents a private investment in the system by a franchisee.
- Rapid system expansion. At a reduced cost to the franchisor, the growth is financed with other people's money. The faster pace of expansion creates a stronger stimulus for economic growth than non-franchised businesses.
- Availability of uniform products and services. Quality assurance at a reasonable price—perhaps the hallmark of a successful franchise system.
- Benefits of interplay between the parties. The local economy capitalizes on the strengths of both the franchisor and the franchisee (i.e., the franchisor's new business stimulates the economy, and expands the franchisee's investment and local know-how).

- Flexibility. Adaptability and resiliency are hallmark characteristics of franchising. Over the last several decades, franchising has been able to absorb and respond to an array of societal changes:
 - Changes in the role of women;
 - Other changes in the labor force;
 - Growth in the number of two-income families;
 - Growth in the desire for convenience throughout our daily lives;
 - The impact of technology, still just at its earliest stage;
 - A greater presence of international competition; and
 - A greater growth of the middle class, particularly in developing economies.

Some economic and social benefits are more common in a developed economy:

- The creation of lower-risk entrepreneurial opportunities;
- Stimulation of growth in related sectors (e.g., suppliers, advertising); and
- Opportunities for private investment via public offerings.
 - While the entry into “developing,” “changing,” “emerging,” or “transitional” economies is less extensive and more recent, its effects are worth examining.⁹
- Entrepreneurial opportunities:
 - A new business model, wherever it flourishes, always represents a reduced/shared risk, and to the extent this concept is understood and absorbed by developing economies, the risk/benefit ratio will be seen as a strong advertisement for investing in franchising.
 - Entrepreneurs can obtain system support they could not otherwise receive, including advertising, training, and strong central direction. Training, particularly for mid-level management, has been especially important. The range of types of assistance franchising offers has been particularly important to Eastern and Central European countries and to the markets in the New Independent States, where entrepreneurialism and free markets were unknown for over two generations. Franchising continues to be a particularly attractive option for smaller businesses; in these newer free market economies, very few business-owners had any experience operating the huge, state-owned industries. To some degree, however, the small business tradition was never altogether eradicated, particularly in Central and Eastern Europe, and that experience can be extrapolated, with appropriate assistance, to a franchise operation.
- The franchisor’s pre-tested systems assure quality and uniformity and provide a structure readily adaptable to another culture. Franchises can fairly rapidly de-

⁹ See, e.g., Ilan Alon & Diana H.B. Welsh, *Global Franchising in Emerging and Transitioning Economies*, 2 INT’L J. BUS. & ECON. 332.

liver consumer goods and services of equal quality and modest price to consumers who have lacked access to such products for years. Again, because in most instances franchise systems deliver food and other products and services that are quite basic, changes that might be required to adjust to the culture can be effected easily. A hamburger becomes a lamb burger in India; the pizza may be topped with squid or tofu to make it more palatable to indigenous tastes in south-eastern Asia. These adaptations are not at a high level of technical difficulty, whether one refers to menus or business services, but they do the job.

- Integration into the global economy carries benefits such as:
 - the potential to expand commercial relationships with other markets relatively swiftly and economically;
 - The potential to encourage a shared sense of societal relationships with other economies; and the impact of icons—the trademarks, trade dress, radio, television, and press and internet advertisements that are among the best known signals of the last fifty years. Behind every powerful icon is a powerful idea.
- Franchising creates jobs at a time when economic upheaval tends to increase the levels of unemployment.
- The removal of job security can, ironically, be just the boost needed for people to take the step into franchising.
- There continues to be a worldwide search for foreign investment; whether in Eastern Europe or sub-Saharan Africa, foreign investment is the common need.

Here is how one high official of a developing country summarized that government's perspective in a private meeting with U.S. officials: "In our country we like franchising. It provides jobs, and that's important to us. It provides opportunities for suppliers to the franchisors, and that creates even more jobs. It gives people familiar places to eat and sleep and shop and that makes foreign tourists more comfortable about visiting us."¹⁰

But there's more. Franchisees are far more advanced than their independent counterparts. They serve reliable and predictable products and services. We have fewer health and safety problems with them. They treat their customers better because they know their franchisors are watching them. They keep reliable records because they have to in order to pay their royalties. They have modern equipment and modern practices.

If we could get all our retailers—in fact, our commercial sector generally—to observe the franchising industry closely, and to emulate it, we would have a better climate for businesses and for consumers in our country.

¹⁰ See Philip Zeidman, *We Like Franchises*, FRANCHISETIMES.COM, (Sept. 2009), <http://www.franchisetimes.com/September-2009/We-Like-Franchises/>.

IV. **Disadvantages to the Franchisor and the Franchisee**

It would be misleading to leave this discussion with the impression that the franchising model provides an unalloyed benefit, either to the franchisor or to the franchisee. It carries potential disadvantages for both. Let us first consider those confronted by the franchisor.

- Return on investment can surely be greater through franchising, as previously noted. However, that assumes that the hope for the franchise system—greater growth of points of distribution—is realized, with the accompanying growth in revenue. Until then, the franchisor will certainly earn less per unit than if operating on a company-owned basis.
- Upfront expenditures and effort can be significant, and often underestimated.
- The sow’s ear-silk purse admonition is relevant but frequently overlooked: unless the business model is solid, franchising is no cure.
- No matter how well-crafted the documents, there will always be less capacity to control retail operations when the operator is an independent businessperson rather than an employee. And when a franchisee becomes complacent, the franchisor has fewer remedial tools at his disposal than would an employer.
- A potentially weaker core community. A successful franchised system depends upon each franchisee perceiving the benefit of cooperation with other franchisees. But some franchises may seek the benefits of “free riding,” and the cost and effort of policing can be burdensome.

It can be more difficult to innovate than in a vertically integrated system.

- From the franchisee’s perspective, the potential disadvantages are likely to be a mixture of psychological and behavioral considerations. The franchised business belongs to the franchisee, with the attendant rewards and risks. But, unlike the independent operator, the franchisee is not free to make his own decisions on a significant number of issues, both long-range and day-to-day.
- An independent operator can determine his own success or failure by dint of effort and involvement, subject to the conditions of the larger market. But a franchisee may be adversely affected by the conduct of other franchisees, which may influence a prospective customer.
- The very strength of franchising—the participation in a horizontal network and the benefit of the vertical flow of advice and planning—can lead to a franchisee’s overreliance on that system, and the failure to develop—or the atrophy of his capacity for—motivation and initiative.

This sort of catalogue of the “pros and cons” of franchising, from the perspectives of the franchisor and the franchisee, can be found in a number of books, articles and

papers. They range from those directed at legal audiences¹¹ to numerous publications targeted to lay audiences.¹²

The statistics cited at the beginning of this Article are powerful evidence that, after weighing the advantages and disadvantages, a large and growing number of “sellers” have elected to become franchisors and “buyers” to become franchisees. The relationship we have been considering is one in which the two parties have themselves determined its parameters. How is that model affected by the introduction of governmental regulation?

V. The Advent of Regulation¹³

In the very earliest years of modern franchising, immediately after World War II, what little attention was devoted to franchising rarely contained an element of dissatisfaction or criticism. Franchisees and their advocates began to express discontent with some aspects of the relationship and the process by which franchises were being marketed in the United States but in a largely muted fashion. It was not until the end of the 1960s that these concerns evoked a legislative or regulatory response.

Governmental regulation has taken two forms: A requirement that franchisors provide prospective franchisees with information about the investment they are contemplating, and a range of restrictions upon the franchisor’s freedom of action in dealing with franchisees.

It is worth examining each form of regulation somewhat more closely.

At the federal level, and thus applicable in every state, the consequences of falling under the Federal Trade Commission Franchise Rule (FTC Rule)¹⁴ is the requirement that a highly detailed “disclosure document,” not unlike a mini SEC prospectus, be provided to the prospective “franchisee” before the initiation of the relationship. That is also true in fifteen states in the United States, where it must also be registered with at least some degree of “approval” by state authorities.¹⁵

Another consequence is that, while there is no “relationship” regulation at the federal level, an even larger number of states regulate this relationship between the parties. A typical provision of state law prohibits termination of the relationship, without regard to what the contract provides, except for “good cause,” a standard that varies in different states. Other typical “relationship” provisions prohibit a refusal to renew the

¹¹ See, e.g., W. MICHAEL GARNER, FRANCHISE AND DISTRIBUTION LAW & PRAC. §§ 1.3, 1.4 (2013).

¹² See MICHAEL SEID & DAVE THOMAS, FRANCHISING FOR DUMMIES 41-43 (2006); Scott Shane, *The Pros and Cons of Franchising Your Business*, ENTREPRENEUR, (May 7, 2013), <http://www.entrepreneur.com/article/226489>.

¹³ For a fuller discussion of this subject, see generally Philip Zeidman & Bret Lowell, *Will the Answers Be Different If the Seller-Buyer Relationship Is a Franchise?*, in LEGAL ASPECTS OF SELLING AND BUYING (3d ed. 2013). See also PHILIP ZEIDMAN & MICHAEL G. BRENNAN, *United States* in GETTING THE DEAL THROUGH: FRANCHISE 2014 (2013).

¹⁴ 16 C.F.R. § 436 (2013).

¹⁵ See *Introduction*, 2009 Bus. Franchise Guide (CCH) ¶ 3000 (discussing state disclosure laws).

relationship or a refusal to permit the dealership or distributorship to be transferred to others or impose some occasionally vague requirements, such as the obligation to treat the buyer “fairly.”¹⁶

Other aspects of the state relationship laws worth noting: They often require minimum standards of notice. Some prohibit discrimination among franchisees. Some also address encroaching on a franchisee’s territory or interfering with association among franchisees. They generally apply to all franchisees, regardless of industry, and the definition of “franchise” may be broader than that in the state’s disclosure law.¹⁷

What is the consequence of failure to comply with one or another of these laws?

At the federal level, the FTC Rule does not grant an aggrieved franchisee the right to bring legal action and seek treble damages. That is because Section 5 of the Federal Trade Commission Act,¹⁸ pursuant to which the FTC Rule was promulgated, is not one of the antitrust laws of the United States. Only the FTC itself can maintain an action for violating the FTC Rule. The FTC may bring civil actions and may seek monetary penalties, injunctive relief, and consumer redress. The FTC can order a rescission, restitution, payment of refunds or damages, or some combination of these. The FTC can also issue cease and desist orders for franchisors that fail to comply with franchise laws and impose civil penalties, on a per diem basis.¹⁹

State registration or disclosure laws do provide a private right of action for franchisees. These laws also authorize the state administrator directly, or through the state attorney general, to bring an action on behalf of the people of the state to enjoin an unlawful act or practice or to enforce compliance with the franchise laws. Available remedies under the franchise laws include denial or revocation of the state franchise registration, consumer redress in the form of actual and sometimes consequential damages, or rescission, injunctions, civil penalties and criminal sanctions against unlawful practices.²⁰

Even in those states without statutory provisions, a number of states have “little FTC statutes,” in some cases making failure to comply with the FTC Rule a per se violation of the state law. In other states, violation of the FTC Rule is simply evidence of a violation of state law.²¹

The individual “relationship” state statutes must be examined with care to identify the precise remedies available to an injured franchisee. One of the most significant is the obligation of repurchase, based typically on compensation to the franchisee for cer-

¹⁶ See generally *State Relationship/Termination Laws*, 2009 Bus Franchise Guide (CCH) ¶ 4000 et. seq. (discussing state relationship laws).

¹⁷ *Id.*

¹⁸ 15 U.S.C. § 45 (2012).

¹⁹ 16 C.F.R. § 436.

²⁰ See, generally, *State Disclosure/Registration Laws*, 2009 Bus Franchise Guide (CCH) ¶ 3000 et. seq. (discussing state relationship laws). see generally *State Relationship/Termination Laws*, 2009 Bus Franchise Guide (CCH) *supra* note 16.

²¹ See, generally, *State Disclosure/Registration Laws*, 2009 Bus Franchise Guide (CCH) ¶ 3000 et. seq. (discussing state relationship laws).

tain assets of the franchised business upon termination or non-renewal without good cause. The required repurchase ranges widely, from physical assets to the business itself; and the calculation of cost, fair and reasonable compensation, commercially reasonable terms, expenses and the like, can also vary.²²

Among the other variables to be considered are: the availability of damages, including lost profits, punitive damages, and unrecouped expenses; availability of injunctive relief; whether a court will order compensation for goodwill; attorney's fees; and, indeed, the retroactivity of the statute and the enforceability of provisions of the agreement such as covenants against competition.²³

VI. International Franchising

Against that background overview of franchising in the United States—how it has grown and why and how it is regulated—let us turn beyond the borders of the United States. While we have seen something of the theoretical benefits that it offers to both developed and developing countries, what do we know of how it has actually developed, and where?

The fifty years during which franchising first became a part of the American culture saw relatively little development outside the country, either by U.S. franchisors or by franchisors in other countries. Except for the very largest companies in the United States, which began extending their tentacles on a sometimes-halting basis into foreign countries, it remained an essentially domestic phenomenon.

The last twenty years, however, have dramatically altered that landscape. In virtually every country in the world, there is now an awareness of franchising, ranging from a modest portion of the overall economy and society in the country to a position rivaling the status it has attained in the United States. The reasons for its growth around the world are essentially the same as they are in the United States: the advantages noted earlier accruing to both the franchisor and the franchisee, taken together with a growing middle class in many markets, a growing “youth market,” and the increasingly homogenized culture of consumption.

Who was leading this wave of expansion?

As before, we begin in the United States, with the expansion of U.S. companies into foreign markets. It is a bit over-simplistic, but largely true, that the large U.S. franchisors have been responsible for this extraordinary movement, but with some intriguing nuances. Of the top 200 franchise companies based in the United States, measured by number of units, 36.2% of their units are already outside of the United States, up from 24% only a decade

²² See, generally, *State Relationship/Termination Laws*, 2009 Bus Franchise Guide (CCH) *supra* note 16.

²³ See *Little FTC Acts—Overview*, 2009 Bus. Franchise Guide (CCH) ¶ 1700 (discussing state relationship laws).

ago.²⁴ The publisher of *Franchise Times*, the principal publication in this industry, estimates that by the end of this decade, the number will be 50%.

It remains true that the larger the franchise network, the higher that percentage is and for obvious reasons—the ability to bear costs and the sophistication and self-confidence required to take one’s system abroad to an alien culture not known to be welcoming. Those qualities are much harder to find in smaller companies than in larger ones.

But a more careful examination of that list of 200 companies shows that it is no longer just the giants. And it is no longer simply the stereotype of foodservice companies and hotels; today, service and retail companies are amply represented.²⁵

Thus to date, cross-border expansion has been largely U.S.-driven. There are still a relatively small number of companies outside of the United States that can aspire to the level of achievements that U.S.-based franchisors have attained. In a ranking of the top 100 global franchises by Franchise Direct, an Ireland-based company which has done the most thorough work on this subject, only a maximum of eleven are based outside the United States.²⁶

But that is changing, and in some cases rapidly. It is no longer only America. Canada was the first foreign entry point for many U.S. franchisors and became the first country outside the United States to develop a significant number of homegrown franchise companies. Before long, countries from every developed continent joined it, with franchise “industries” in a few instances rivaling in importance the position they have achieved in the United States.²⁷

In some countries the number of franchise chains is very large—not surprisingly, China is one of them.²⁸ But the number of franchise chains is not always a function of the size of the population. On a per capita basis, Australia, for example, may be the most franchised country in the world, but the size of its systems is much smaller than those in the United States.²⁹ The traditional dominance of U.S. brands has in some countries, such as Brazil, given way to a predominantly indigenous body of franchises.³⁰

Although there are currently few non-U.S. franchise companies that are in the same league as the U.S. giants, they are appearing on the horizon. Consider Jollibee’s, the largest

²⁴ 2013 *Franchise Times Top 200 Global Franchise Systems*, FRANCHISE TIMES, Oct. 2013, at 1, 4.

²⁵ *Id.*

²⁶ 2013 *Top 100 Global Franchises – Rankings*, FRANCHISE DIRECT, <http://www.franchisedirect.com/top100globalfranchises/rankings/> (last visited Dec. 31, 2013).

²⁷ PriceWaterhouseCoopers Australia, *How is franchising driving business growth?* FRANCHISE SECTOR INDICATOR (May 2011), <http://www.pwc.com.au/industry/franchising/assets/franchise-sector-indicator/Franchise-Sector-Indicator-Aug11.pdf>.

²⁸ Yan Yiqi, *Franchise Heat*, CHINA NEWS DAILY (June 6, 2011), http://www.chinadaily.com.cn/business/2011-06/24/content_12772247.htm.

²⁹ Tony Featherstone, *Is Australia Too Franchised?*, SYDNEY MORNING HERALD (Aug. 10, 2010), <http://www.smh.com.au/small-business/managing/blogs/the-venture/is-australia-too-franchised-20100809-11tya.html>.

³⁰ See Philip Zeidman, *Latin Beat*, FRANCHISETIMES.COM (Sept. 2012), <http://www.franchisetimes.com/September-2012/Latin-Beat/>.

fast food chain in the Philippines, operating a nationwide network of more than 750 stores and now expanding internationally.³¹

The boldest among those expanding beyond their own borders are venturing into the richest market, the United States. Kumon of Japan, for example, the world's largest after-school program, is in over forty countries and has over 1,500 U.S. locations.³² Among the more notable developments in recent years is the extent to which immigrant populations, especially in cities in which they have settled in sizeable numbers, have served as a catalyst and a magnet, not only for U.S. franchisors targeting that market but for franchisors from their home country. Guatemala-based Pollo Campero, the world's largest Latin chicken restaurant chain, now operates over 300 restaurants in twelve countries around the globe, with more than fifty in the United States.³³

VII. Regulation of International Franchising

As we have seen, the regulation of franchising in the United States had largely assumed its present shape and texture by the end of the 1980s. Both disclosure laws and relationship laws were sufficiently similar to one another that experiences under the laws of one of the states could usually be extrapolated to the laws of another, and, in the realm of disclosure, experience under the FTC Rule was broadly applicable to state "disclosure" laws, and vice versa. Indeed, the Franchise and Business Opportunity Project Group of the North American Securities Administrators Association has performed yeoman service by urging states with disclosure statutes to bring them more closely into conformity with one another and, in the process of doing so, align them more closely with the FTC Rule.³⁴

As to the extent of material on the basis of which to interpret the regulation, consider the FTC Rule. It was based on public hearings held over a two-week period, followed by receipt of written statements and comments over a ninety-day period. The record of the proposed rule and the revised rule, together with the hearings and comments, exceeds 30,000 pages (almost 2,000 pages of transcript, more than 5,000 pages of consumer submissions, approximately 5,000 pages contributed by industry members, and an equal amount from other government agencies and academics).³⁵ The Commission's "Statement

³¹ JOLLIBEE, <http://www.jollibee.com.ph/about-us/> (last visited Feb. 14, 2014); *see also* Philip Zeidman, *Sense of Place*, FRANCHISETIMES.COM (Apr. 2013), <http://www.franchisetimes.com/April-2013/Sense-of-Place/>.

³² Press Release, Kumon N. Am., Inc., Entrepreneur Magazine Ranks Kumon No. 1 Education Franchise for 13th Consecutive Year (Jan. 7, 2014), *available at* <http://www.kumonfranchise.com/PressRelease/Release2014-0107.aspx>.

³³ POLLO CAMPERO, <http://www.campero.com/about-us.aspx> (last visited Feb. 14, 2014); *see also*, Philip F. Zeidman, *Plan B*, FRANCHISETIMES.COM (Mar. 2013), <http://www.franchisetimes.com/March-2013/Plan-B/>.

³⁴ *See* NORTH AM. SEC. ADM'RS ASS'N, FRANCHISE RESOURCES, <http://www.nasaa.org/industry-resources/corporation-finance/franchise-resources/>.

³⁵ *Chapter I: History of Proceedings*, 2009 Bus. Franchise Guide (CCH) ¶ 6301.

of Basis and Purpose”³⁶ provides invaluable commentary and explanation, and subsequent revisions have been subject to similar processes and documentation.

While reasonable observers might differ on whether a particular state law was justified on the basis of the factual and legal arguments adduced in support of it by its proponents, the process by which these laws were advanced generally gave ample opportunity for debate, and the legislative history provided material for subsequent interpretation and ratiocination.

Outside the United States, however, the approach to legislative regulation of franchising presents, by and large, a more variegated picture and one that is not easy to rationalize. And there is nothing approaching the trove of material on the basis of which participants, counsel, and observers can seek to interpret the laws and regulations.

In the 1980s and 90s, and in the last decade, there has been a proliferation of franchise laws. In many cases, these were based upon the U.S. model, especially from the point of view of disclosure. In some cases they arose from genuinely felt concerns about abuses by scoundrels, or by franchisors that promised more than they could or intended to deliver. In many cases, however, they arose from a simplistic notion that, because franchise regulation had existed in the United States since essentially the 1970s, and because that had not apparently deterred the growth of franchising, the handmaiden of successful franchising must somehow be regulation of it.

One can argue that that is simply wrongheaded, that all that is needed by way of a legal framework in order for franchising to thrive in a country is a sound system of protecting trademarks and other intellectual property, a recognition of the sanctity of contracts, and a system for resolving disputes which provides confidence to both parties that they will be able to obtain effective recourse.

The problem is that there are not enough countries where those elements can truly be said to exist. And it is also, regrettably, the case that logic is not typically the determining factor as to why such legislation will be enacted and adopted. In many cases, it simply emerges from the notion that “this is the way to show the rest of the world that we have become part of the global economy.”

VIII. Examination of National Regulation

Let’s examine what has happened. It should not be surprising that one of the first countries to regulate outside the United States was its northern neighbor. But, unlike the United States, no federal regulation has been forthcoming in Canada (indeed, only provincial collaboration would make that possible). Even though extensive work has been done to advance such an effort, as more individual provinces act alone, that goal seems increasingly unlikely. Alberta moved first in 1971 with disclosure requirements similar to those in the

³⁶ Promulgation of Trade Regulation Rule and Statement of Basis and Purpose, 43 Fed. Reg. 59621 (Dec. 21, 1978) (to be codified at 16 C.F.R. pt. 436).

United States.³⁷ The province revamped the legislation in 1995 to do away with governmental oversight and also to incorporate franchise relationship provisions.³⁸ It was followed by Ontario in 2000, which added to the itemized subjects of disclosure a requirement that the information be “accurate, clear and concise” and that any material change be reported as soon as discovered.³⁹ The franchise laws of Prince Edward Island (effective 2006), New Brunswick (effective 2011), and Manitoba (effective 2012), are patterned after those in Ontario, containing both disclosure obligations and some limited relationship provisions.⁴⁰

In 1989, France became the first country outside the Americas to regulate franchising, with Loi Doubin.⁴¹ That law requires disclosure to a prospective franchisee, to enable an informed decision with “full knowledge of the relevant facts.”⁴² In addition to information similar to that required in the United States, it contains a unique feature calling for a “market study” to reflect the prospects in the general and local market; the scope of that obligation remains a subject of dispute to this day.⁴³ The law provides for criminal fines and sanctions, but no civil remedies.⁴⁴

Mexico’s franchise law dates to 1994, and is an element of its Industrial Property Law.⁴⁵ Principally a set of disclosure obligations, it contains provisions for a fine in the event of violations; however, the franchisee must first send a written request for the

³⁷ Franchises Act, R.S.A. 1971 c. F-38 (Can.); see George J. Eydt & Edward Levitt, *The Devil is in the Details: How Canadian and U.S. Franchise Legislation Differs*, 32 FRANCHISE L.J. 237, 237 (2013).

³⁸ Franchises Act, R.S.A. 1995, c. F-17.1 (Can.).

³⁹ Arthur Wishart Act, S.O. 2000, c. 3 (Can.).

⁴⁰ Franchises Act, R.S.M. 2012, c. F-156 (Can.); Franchises Act, R.S.N.B. 2007 c. F-23.5 (Can.); Franchises Act, R.S.P.E.I. 1988, c. F-14.1 (Can.); Franchises Act Regulations, P.E.I. Reg. EC2006-232 (Can.).

⁴¹ Loi no 89-1008 du 31 décembre 1989 relative au développement des entreprises commerciales et artisanales et à l’amélioration de leur environnement économique, juridique et social [Law No. 89-1008, concerning the development of commercial and artisanal enterprises and the improvement of their economic, legal and social environment], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], Jan. 1, 1990 (Fr.); Décret n° 91-337 du 4 avril 1991 portant application de l'article 1er de la loi n° 89-1008 du 31 décembre 1989 relative au développement des entreprises commerciales et artisanales et à l'amélioration de leur environnement économique, juridique et social, [Decree No. 91-337 of 4 April 1991] JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], 6 April 1991 (a correction to the Decree was published in the Journal Officiel of 4 May 1991) (Fr.); *Franchise Disclosure Law*, 2009 Bus. Franchise Guide (CCH) ¶ 7135-7136. Note that this and all subsequent citations to foreign laws in the Business Franchise Guide are to English translations of those laws.

⁴²Loi no 89-1008 du 31 décembre 1989 (Fr.) *supra* note 41, art. 1.

⁴³ Décret n° 91-337 du 4 avril 1991 (Fr.) *supra* note 41, at art. 1.

⁴⁴ *Id* at art. 2.

⁴⁵ Ley de la Propiedad Industrial [LPI] [Law on Industrial Property], *as amended*, Diario Oficial de la Federación [DO], 27 de Juno de 1991 (Mex.); *Franchise Provisions, Law on Industrial Property*, 2009 Bus. Franchise Guide (CCH) ¶ 7205.

disclosure document.⁴⁶ There is a provision for nullification of the agreement and the payment of damages or losses in the event the document is incorrect.⁴⁷

The first of the countries within the sphere of influence of the former Soviet Union to act, Albania, adopted a highly ambiguous law in 1994.⁴⁸ It does not specify the precise information required but contains a general obligation that the parties are required to exchange information on all matters germane to the franchise business, but with no indication of the time frame.⁴⁹

In addition to rather standard disclosure obligations, the Brazilian franchise law, enacted in 1995, contains a unique provision requiring the franchisor to provide the characteristics of an “ideal franchisee.”⁵⁰ This provision continues to be the subject of some puzzlement in the franchise community. While Spain first enacted franchise legislation in 1996, its pre-contractual disclosure obligations were not included until 1998.⁵¹ A key feature of the law is the Franchisors’ Register, to which a franchisor is required to submit specified information on an ongoing basis; failure to do so can result in a sizable fine.⁵²

Russia’s 1996 law addresses the relationship between the franchisor and the franchisee, and requires a registration, but it has raised more questions than answers.⁵³ The most controversial provisions have been those imposing obligations upon the franchisor for shortcomings in the quality of goods or services provided by the franchisee, apparently without regard to any efforts to insulate the franchisor from such liability.⁵⁴ Subsequent amendments relate to pricing, with others in flux.⁵⁵

Indonesia’s regulation was adopted in 1997, addressing both pre-contractual disclosure and relationship issues.⁵⁶ In 2007, it was amended to put the onus on the

⁴⁶ *Franchise Provisions, Law on Industrial Property*, 2009 Bus. Franchise Guide (CCH) ¶ 7205.

⁴⁷ *Id.*

⁴⁸ KODI CIVIL [C. CIV.] art. 1056 et seq., *Fletorja zytare*, No. 7,850 (1994) (Alb.).

⁴⁹ *Id.*

⁵⁰ Lei no 8.955, de 15 de Dezembro de 1994, Diário Oficial da União [D.O.U.] de 16.12.1994 (Braz.); *Franchising Law*, 2009 Bus. Franchise Guide (CCH) ¶ 7015.

⁵¹ Commercial Retail Law art. 62 (B.O.E. 1996, 7) (Spain); *Disclosure/Registration Law*, 2009 Bus. Franchise Guide (CCH) ¶ 7255.

⁵² *Disclosure/Registration Law*, 2009 Bus. Franchise Guide (CCH) ¶ 7255.

⁵³ GRAZHDANSKII KODEKS ROSSIISKOI FEDERATSII [GK RF] [Civil Code] ch. 54 (Russ.); *Franchise Law*, 2009 Bus. Franchise Guide (CCH) ¶ 7235.

⁵⁴ See GRAZHDANSKII KODEKS ROSSIISKOI FEDERATSII [GK RF] (Russ.), *supra* note 53, at art. 1034; *International Laws and Regulation*, 2009 Bus Franchise Guide (CCH) ¶ 7230.

⁵⁵ *Id.* at art. 1033 (2012 amend.) (Russ.) (the amendment serves to eliminate the contradiction between Russia’s Federal Law No.135-FZ on Protection of Competition - which allows a franchisor to set minimum and maximum resale prices, and the prior version of the Russian Civil Code’s - which prohibits the setting of such prices, by removing the restrictions in the Civil Code and allowing franchisors to impose such limitations).

⁵⁶ Government Regulation on Franchise No. 16/1997 (Indon.); Minister of Trade and Industry Decree, no. 259/MPP/Kep/7/1997 (1997) (Indon.) regarding the Provisions and Procedures for the Implementation of Franchise Business Regulation.; *Introduction—Indonesia*, 2009 Bus. Franchise Guide (CCH) ¶ 7140-7145

franchisor to register the franchise-offering prospectus and the franchisee to register the Franchise Agreement.⁵⁷

Moldova's two sets of laws (1997 and 2003) are unique.⁵⁸ Information is required, but without any specified timeframe, and is apparently imposed upon the franchisee, as well as the franchisor. The same pattern exists in the relationship aspects of the laws, in which confidentiality and good faith obligations are imposed upon both parties.⁵⁹ The statutes allow for the reduction of payments made by the franchisee if the franchisor does not fulfill its obligations.⁶⁰

China's original (1997) regulation of franchising proved wholly inadequate for what was then an unfamiliar form of doing business.⁶¹ The subsequent refinements of the law have brought it more into line with general international schemes of regulation, calling for disclosure of specified information as well as addressing certain aspects of the ongoing relationship between the franchisor and the franchisee.⁶² The principal focus of international attention, however, has been on the treatment of prerequisites to franchising, including the requirement (discussed elsewhere in this Article)⁶³ of operation of company-owned units.

Romania's 1998 Ordinance and Law contains both a disclosure component (again, vaguely referring to "sufficient time in order to make an informed decision") and a relationship provision which requires a minimum term, notice of non-renewal, and other components of the franchise agreement itself.⁶⁴

Under the Kyrgyzstan 1998 Civil Code provision, the franchisor has only two obligations: to provide a technical and commercial document to allow the franchisee to exercise its rights and to provide further detail to the franchisee or its employees regarding those rights.⁶⁵ The franchisee, by contrast, has many more obligations to fulfill.⁶⁶

⁵⁷ See Government Regulation on Franchise, No. 42/2007, Statute Book of the Republic of Indonesia Year 2007 No. 90, July 23, 2007 (Indon.).

⁵⁸ The Law of the Republic of Moldova on Franchising no. 1335 (1997) (Mold.); CODE CIVIL [C. CIV.] ch. XXI (Mold.).

⁵⁹ The Law of the Republic of Moldova on Franchising (Mold.) *supra* note 58, at ch. III.

⁶⁰ CODE CIVIL [C. CIV.] art. 1179 (Mold.).

⁶¹ Shang ye te xu jing ying guan li ban fa (shi xing) (商业特许经营管理办法 (试行)) [Interim Measures on Administration of Commercial Franchise Operations] (promulgated by Ministry of Domestic Trade on Nov. 14, 1997) Order No. 124 (China); *Introduction—China*, 2009 Bus. Franchise Guide (CCH) ¶ 7060.

⁶² Shang ye te xu jing ying guan li tiao li (商业特许经营管理条例) [Administrative Regulation on Commercial Franchise] (promulgated by the State Council, Feb. 6, 2007, effective May 1, 2007) ST. COUNCIL GAZ., May 23, 2007 (China).

⁶³ See *infra* Part XII.C.2.

⁶⁴ Lege nr. 79 din 9 aprilie 1998 pentru aprobarea Ordonantei Guvernului nr. 52/1997 privind regimul juridic al francizei, [Law n. 79/1998 approving Government Ordinance n. 52/1997 regarding the legal status of franchises] Monitorul Oficial [M.O.], 13 April 1998, n. 147 (Rom.), 2009 Bus. Franchise Guide (CCH) ¶ 7225.

⁶⁵ CODE CIVIL [C. CIV.] c. 44, art. 870 (Kryg).

⁶⁶ *Id* at art. 871.

In 1998, Malaysia enacted a franchising law covering both disclosure and relationship.⁶⁷ The detail is extensive, including such matters as discrimination among franchisees, segregation of promotional payments, minimum term, etc.⁶⁸ The disclosure provisions are not unusual, but are among the most comprehensive in the world.⁶⁹

After a long history of a self-regulatory code, Australia adopted a Franchising Code of Conduct in 1998, addressing both disclosure and relationship features.⁷⁰ The disclosure requirements are extensive, and vary depending upon the expected annual turnover of the business.⁷¹ The Code itself is quite comprehensive, and has undergone numerous reviews by the Australian Government to review its efficacy (most recently, in 2013), and was amended in 2008 and 2010.⁷²

The regulations in Belarus (1998) contain obligations regarding the relationship between the parties, but no pre-sale disclosure requirements.⁷³ The “relationship” provisions consist entirely of the standard obligations of each party to the other to produce a workable franchise system.⁷⁴

Turkmenistan’s 1998 regulation sets out the parties’ obligations, which are both few and simple.⁷⁵ The disclosure requirement does not specify the type of information to be disclosed but only states that each party is obligated to familiarize the other regarding the respective obligations “candidly and fully.”⁷⁶

Taiwan’s 1999 “Standards Governing the Disclosure of Information by Franchisors” requires disclosure of information of the sort generally familiar from other laws.⁷⁷ Macau’s law of the same year contains both disclosure and relationship requirements.⁷⁸ The Macau law was modeled after the Brazilian franchise regulation.⁷⁹

⁶⁷ Franchise Act 1998, Act no. 590 (given Royal Assent 24 Dec. 1998) (Malay); 2009 Bus. Franchise Guide (CCH) ¶ 7185.

⁶⁸ See Franchise Act 1998 (Malay.) *supra* note 67.

⁶⁹ See *id.*

⁷⁰ *Trade Practices (Industry Code -- Franchising) Regulations 1998* (Cth) sch (Austral.); *Introduction—Australia*, 2009 Bus. Franchise Guide (CCH) ¶ 7000.

⁷¹ See *Trade Practices (Industry Code -- Franchising) Regulations 1998* (Austral.) *supra* note 70 at pt 2.

⁷² Alan Wein, Review of the Franchising Code of Conduct: Report to the Hon Gary Gray AO MP, Minister for Small Business, and the Hon Bernie Ripoll MP, Parliamentary Secretary for Small Business (Apr. 30, 2013) (Austral.); *Trade Practices (Industry Codes – Franchising) Amendment Regulation 2007* (No. 1) (Cth) (Austral.); *Trade Practices (Industry Codes – Franchising) Amendment Regulation 2010* (No. 1) (Cth) (Austral.).

⁷³ CODE CIVIL [C. CIV.] ch. 53 (Belr.).

⁷⁴ *Id.* at art. 910.

⁷⁵ CODE CIVIL [C. CIV] art. 629-636 (Turkm.).

⁷⁶ *Id.* at art. 632.

⁷⁷ TAIWAN FAIR TRADE COMM’N., GUIDELINES ON THE DISCLOSURE OF INFORMATION BY FRANCHISORS art. 4 (1999); *Standards Governing Disclosure of Information by Franchisors*, 2009 Bus. Franchise Guide (CCH) ¶ 7262.

⁷⁸ COMMERCIAL CODE, tit. VIII (Mac.)

⁷⁹ This language (The disclosure provisions are based upon China’s franchise legislation, which suggests that the otherwise vague requirements of “adequate advance” information and “complete” and “truthful”

The relationship provisions are imposed on both parties and address such matters as securing advertising of the franchise network, compensating the franchisee for any new knowledge or innovations, improving the condition of the network, and compensating for the obligation of post-term noncompetition.⁸⁰

In Azerbaijan, a 2000 regulation contains a presale disclosure requirement but neither specifies the information to be disclosed nor sets out a time frame for doing so.⁸¹ The parties must determine for themselves the scope of the obligation to “acquaint each other plainly and completely with conditions related to franchise, especially with franchise system and honestly inform each other.”⁸² The relationship provision is skeletal, but it does provide that, if the franchisor does not fulfill the duties set out in the agreement, the franchisee has the right to reduce royalties at a rate determined by an “independent expert.”⁸³

Latvia’s 2000 requirements are under its Commercial Law and contain both disclosure and relationship provisions.⁸⁴ They impose obligations upon both parties and contain such imprecise requirements as “safeguarding the viability of the business” and “preserving the good reputation.”⁸⁵ Several different regulations affect franchising in Lithuania, most directly the version of the Civil Code enacted in 2000.⁸⁶ The panoply of legislative acts relating to taxation, unfair competition and intellectual property protection must be examined with some care. The requirements in the Georgia Civil Code of 2001 are vague: the parties are required to “openly and completely” communicate with each other regarding the circumstances of the franchised business.⁸⁷ The governance of the relationship of the parties is equally broad, imposing some duties on both franchisor and franchisee.⁸⁸ Estonia’s Law of Obligations Act (2002) does not provide for disclosure, but it does cover certain aspects of the relationship.⁸⁹

Japan’s regulatory treatment of franchising dates back to 1983, when the Japan Fair Trade Commission issued guidelines.⁹⁰ The 2002 replacement of those guidelines, together with the Medium and Small Retail Commerce Protection Act (but only if the relationship

information will be interpreted in a way to comport with the Chinese approach.) should be deleted, as the Macau law was modeled after the Brazilian franchise regulation.

⁸⁰ See COMMERCIAL CODE (Mac.) *supra* note 78.

⁸¹ CODE CIVIL [C. CIV.] ch. 35 (Azer.).

⁸² *Id* at art. 726.

⁸³ *Id* at art. 730.

⁸⁴ COMMERCIAL LAW ch. 7 (Lat.)

⁸⁵ *Id* at §476.

⁸⁶ CODE CIVIL [C. CIV.] ch. XXXVII (Lith.)

⁸⁷ CODE CIVIL [C. CIV.] art. 610 (Geor.).

⁸⁸ *Id* at art. 607-614.

⁸⁹ Võlaõigusseadus [Law of Obligations Act], 53 R.T. 336 (2002) (Est.).

⁹⁰ JAPAN FAIR TRADE COMM’N, GUIDELINES CONCERNING THE FRANCHISE SYSTEM FROM THE VIEWPOINT OF THE ANTIMONOPOLY ACT (1983).

falls within the statutory definition), address both disclosure and relationship aspects.⁹¹ There are unusually detailed aspects including business hours, business days, the structure of the business, and indemnification in the event the business is not profitable.⁹² In addition, a number of other laws affect the relationship.

South Korea's pattern of regulation began with its Franchising Guidelines adopted in 1997 by the South Korean Fair Trade Commission.⁹³ They were replaced by the Act on Fairness in Franchise Transactions (Franchise Act), which became effective in 2002, and was amended in 2008 and again in 2010.⁹⁴ That act contains both disclosure requirements and relationship obligations. Certain disclosure information is required in all cases, but further information is required only in the event of a franchisee's request.⁹⁵ The relationship provisions are unusually comprehensive, requiring that the franchisor engage in ongoing efforts to improve sales techniques, and imposing a obligations to provide products and services at a reasonable price and to use best efforts to resolve disputes.⁹⁶ There is a provision to establish a "Franchise Business Transaction Dispute Mediation Council" to resolve franchise transactions disputes by mediation.⁹⁷ The Franchise Act was amended in February 2014 to address franchise relationship issues and heighten disclosure requirements.⁹⁸

Kazakhstan's 2002 "Law on Complex Business License," together with a chapter of the Civil Code of Kazakhstan, address the franchise relationship, but in an uncertain fashion.⁹⁹ It would appear that the disclosure obligations of the franchisor are limited to the disclosure of the rights provided under the franchise agreement and an obligation to inform the prospective franchisee of the confidential nature of information provided in connection with the franchise.¹⁰⁰ The statutory pattern is peculiar in several respects, including the disproportionate number of obligations of the franchisee and some unusual rights of the franchisor (including the right to conclude the contract unilaterally).¹⁰¹

⁹¹ JAPAN FAIR TRADE COMM'N, GUIDELINES CONCERNING THE FRANCHISE SYSTEM FROM THE VIEWPOINT OF THE ANTIMONOPOLY ACT (2002) (hereinafter JAPAN 2002 FRANCHISE GUIDELINES); Medium and Small Retail Sale Business Promotion Law (Act No. 101/1973) (Japan).

⁹² JAPAN 2002 FRANCHISE GUIDELINES *supra* note 91.

⁹³ KOREAN FAIR TRADE COMM'N, GUIDELINES ON INTERNATIONAL CONTRACTS (1997).

⁹⁴ Fair Franchise Transactions Act, Act No. 6704, May 13, 2002, *amended by* Act No. 10168, Mar. 22, 2010 (S. Kor.); Enforcement Decree of the Fair Franchise Transactions Act, Presidential Decree No. 23475, Jan. 1, 2012, *available at* <http://eng.ftc.go.kr/legalauthority/recentlaw.jsp?pageId=0401>.

⁹⁵ Fair Franchise Transactions Act, Act No. 6704 (S. Kor.) *supra* note 94, at art. 9.

⁹⁶ *Id* at art. 5.

⁹⁷ *Id* at art 16.

⁹⁸ Press Release, Korea Fair Trade Comm'n, National Assembly Approves Amendments to the Fair Trade Act (July 22, 2013), *available at* <http://eng.ftc.go.kr/>.

⁹⁹ On Complex Entrepreneurial Licenses (Franchising) (Law No 330/2002) (Kaz.); CODE CIVIL [C. CIV] ch.45 (Kaz.); *Introduction—Kazakhstan*, 2009 Bus. Franchise Guide (CCH) ¶ 7160-et seq.

¹⁰⁰ On Complex Entrepreneurial Licenses (Franchising) *supra* note 99, at art. 15; *id* at art. 18.

¹⁰¹.On Complex Entrepreneurial Licenses (Franchising) *supra* note 99 at art. 17; *id* at art. 14.

The Mongolian Civil Code imposed both pre-sale disclosure requirements and ongoing relationship provisions in 2002.¹⁰² The disclosure provision, however, merely requires that “all necessary information” must be exchanged and that confidentiality must be preserved.¹⁰³ Angola’s 2003 law does not provide for pre-contractual disclosure but does address the relationship between the parties in a fairly non-controversial fashion.¹⁰⁴

Italy’s 2004 regulation of franchise includes both disclosure obligations and certain relationship requirements.¹⁰⁵ Some of these requirements are quite vague, and there have been reports of an obligation to exercise good will, to be forthright and honest, etc. The franchisor may refuse to provide certain information but must justify its refusal.¹⁰⁶ There are also requirements related to levels of expertise and know-how that remain uncertain in terms of scope.¹⁰⁷ The term must be “long enough to allow the amortization of the investment.”¹⁰⁸ The Franchise Regulation in effect controls entry by specifying which provisions are applicable to foreign franchisors that have operated only outside Italy.¹⁰⁹

Vietnam’s 2005 law is comprehensive, including an obligation for a “franchise description” document.¹¹⁰ The rights and obligations of both the franchisor and the franchisee are treated at some length, and there are provisions for both.¹¹¹ The principal method of enforcing these obligations appears to be the right of a franchisee to file a complaint against a franchisor with the authorities.¹¹²

Sweden’s 2006 franchise disclosure law spells out the information required to be provided to the franchisee “well before a franchise agreement” is executed.¹¹³ Belgium’s 2006 regulation of franchising has two parts: the first regards disclosure of significant contractual provisions, and the second addresses “facts contributing to the correct appreciation of the agreement.”¹¹⁴ Within two years of executing the franchise, the franchisee can request nullification on the basis of asserted non-compliance with the disclosure requirements.¹¹⁵

¹⁰² CODE CIVIL [C. CIV] ch. 29 (Mong.).

¹⁰³ *Id* at art. 334.

¹⁰⁴ Law on Distribution, Agency Franchising and Concession Agreements (Law No. 18/2003) (Angl.).

¹⁰⁵ Legge 6 maggio 2004, n. 129 (It.); *Introduction—Italy*, 2009 Bus. Franchise Guide (CCH) ¶ 7150.

¹⁰⁶ *See, generally*, Legge 6 maggio 2004 (It.) *supra* note 105, at art. 6.

¹⁰⁷ *See, generally*, Decreto Legislativo 10 febbraio 2005, n. 30 (It.).

¹⁰⁸ Legge 6 maggio 2004 (It.) *supra* note 105, at art. 3.

¹⁰⁹ Decreto 2 settembre 2005, n. 204 (It.); 2009 Bus. Franchise Guide (CCH) ¶ 7153

¹¹⁰ Commercial Law No. 36/2005/QH11, art. 284-291 (Viet).

¹¹¹ *Id* art. 288-289.

¹¹² Decree Making Detailed Provisions For Implementation of the Commercial Law With Respect to Franchising Activities (Decree No. 35/2006), art. 26 (Viet.). 2009 Bus. Franchise Guide (CCH) ¶ 7282.

¹¹³ Lag om franchisegivares informationskyldighet (Svensk författningssamling [SFS] 2006:484) (Swed.); *Introduction—Sweden*, 2009 Bus. Franchise Guide (CCH) ¶ 7257.

¹¹⁴ Loi relative à l'information précontractuelle dans le cadre d'accords de partenariat commercial [Law relative to pre-contractual information in the framework of agreements of commercial partnership] of Dec. 19, 2005. MONITEUR BELGE [M.B.] [Official Gazette of Belgium] February 16, 2006, 2nd. ed., 7563; *Introduction—Belgium*, 2009 Bus. Franchise Guide (CCH) ¶ 7007.

¹¹⁵ *Introduction—Belgium*, 2009 Bus. Franchise Guide (CCH) ¶ 7007.

South Africa's 2011 law is unique in including the franchisee within the country's broad approach to consumer rights.¹¹⁶ A disclosure obligation is set out in some detail, but with somewhat unclear remedies for enforcement. References to "equality," "reasonableness," and "unjust pricing" provide ample opportunity for interpretation and disputes.¹¹⁷

One of the most recent franchise laws is Tunisia's 2010 Act and Decree on "Distributed Trade."¹¹⁸ It contains both a disclosure provision and relationship obligations. They are quite basic but reflect that country's efforts to establish itself as part of the international business community. As noted elsewhere in this Article, however, the degree to which the administrative machinery for approving the sale of franchises will be applied, especially in the foodservice industry, remains a somewhat unsettled area.

Ukraine's 2011 law solely regulates the relationship between the parties, with traditional allocations of rights and responsibilities.¹¹⁹ It has no disclosure requirement. Some "special situations" should be noted:

- In the European Union the treaty establishing the European Economic Community governs competition law.¹²⁰ An early decision by the European Court of Justice held that provisions essential to the functioning of a franchising system do not constitute unlawful restrictions on competition.¹²¹ A Franchise Block Exemption was replaced by the broader Vertical Restraints Block Exemption, and the Commission has set out obligations in its Guidelines on Vertical Restraints that it deems necessary to protect the franchisor's intellectual property rights and, therefore, fall under the block exemption and may be contained in agreements.¹²² Depending upon the structure of the relationship franchisors may need to study

¹¹⁶ Consumer Protection Act 68 of 2008 (S. Afr.); *Introduction—South Africa*, 2009 Bus. Franchise Guide (CCH) ¶ 7244.

¹¹⁷ See Consumer Protection Act 68 of 2008 (S. Afr.) *supra* note 116.

¹¹⁸ Loi 2009-69 du 12 août 2009 de relative au commerce de distribution [Law No. 2009-69 of Aug. 12, 2009 on trade distribution], JOURNAL OFFICIEL DE LA RÉPUBLIQUE TUNISIENNE [J.O.] [Official Gazette of Tunisia], Feb. 5, 2009, n. 65, p. 2349 (Tunis.); Décret 2010-1501 du 21 juin 2010 portant fixation des clauses minimales obligatoires des contrats de franchise ainsi que des données minimales du document d'information l'accompagnant [Decree 2010-1501 of 21 June 2010 fixing the compulsory minimal clauses of the franchise contracts as well the minimal data of the joint information document.], JOURNAL OFFICIEL DE LA RÉPUBLIQUE TUNISIENNE [J.O.] [Official Gazette of Tunisia] Jun. 22, 2010, n. 50, p. 1744 (Tunis.).

¹¹⁹ See Anna Tsirat, *Ukraine* in INTERNATIONAL FRANCHISING p.UKR/1-3 (Dennis Campbell ed., 2nd ed. 2011).

¹²⁰ Treaty Establishing the European Economic Community, Belg.-Ger.-Fr.-It.-Lux.-Neth., Mar. 25, 1957, 298 U.N.T.S. 11.

¹²¹ Case C-161/84., Pronuptia de Paris GmbH v Pronuptia de Paris Irmgard Schillgallis, 1986 E.C.R. 353.

¹²² Commission Regulation 330/10, Guidelines on Vertical Restraints, 2010 O.J. (L102) 1, 13-16.

Commission's treatment of certain provisions (e.g., resale price maintenance, exclusivity, product sourcing, and non-competition covenants).¹²³

- Some countries have statutes that refer to franchising but with some evidence that the country's laws do not necessarily depend upon that characterization (e.g., Barbados, Saudi Arabia).¹²⁴ Others have "Guidelines," which essentially comment upon which provisions might implicate the country's anti-competition provisions (e.g. Venezuela, whose 2000 Guidelines law are heavily contingent upon the provisions of the agreement).¹²⁵
- Most countries where franchising is present have a "franchise association," and most of those have adopted one version or another of a code of conduct. Typically, those do not have the force and effect of law and are applicable only to members of the association, but they can be influential in courts' views of "acceptable practices" in franchising; and over a period of time they can be reflected in a franchise law.¹²⁶

IX. Disparities and Other Concerns

The pattern of non-U.S. regulation of franchising can thus be said to more nearly resemble a kaleidoscope. Even in the one region of the world, the European Union, where one might expect an orderly and more or less symmetrical approach, it does not necessarily exist. As one commentator has observed:

Franchising has been identified by the European Commission's Competition Directorate as being of great economic importance to the European Union. Indeed, European jurisprudence, such as the well-known *Pronuptia* case and decisions of the Commission, such as *Yves Rocher*, *ComputerLand*, *ServiceMaster* and *Charles Jourdan*, all underscore the important role of franchising in furthering the establishment of a single market in the EU. However, although European competition law treats franchising in a relatively benign manner, member state law takes a somewhat different and entirely heterogeneous approach. Eight EU member states have franchise-specific regulatory regimes, but no two are the same. The

¹²³ See Robert A. Lauer, Dr. Karsten Metzloff, & Tao Xu, Foreign Competition Laws and Their Effect on Transnational Franchise Relationships at the Am. Bar Ass'n Forum on Franchising (Oct. 17, 2013).

¹²⁴ Franchises (Registration and Control) Act, ch. 179A . (1 L.R.O. 1991) (Barb.); *see Laws and Regulations*, SAUDI ARABIA MINISTRY COMMERCE & INDUSTRY, <http://www.mci.gov.sa/en/LawsRegulations/Pages/default.aspx> (last visited May 27, 2014) (providing various agency laws and regulations).

¹²⁵ Lineamientos para la Evaluacion de Contratos de Franquicia [Guidelines for Assessing Franchise Agreements], GACETA OFICIAL DE LA REPUBLICA DE VENEZUELA [G.O.] No. 5,431, Ruling No. SPPLC/038-99, 30, Jan. 7, 2000 (Venez.), available at <http://www.pgr.gov.ve/dmdocuments/2000/5431.pdf>; *Guidelines for Evaluating Franchise Agreements*, 2009 Bus. Franchise Guide (CCH) ¶ 7275.

¹²⁶ Philip Zeidman, *Codes of Ethics and International Franchising: Who Cares?*, FRANCHISING WORLD, Apr. 2004, 32.

remaining 19 member states regulate franchising entirely by the application of general law, again with little homogeneity.¹²⁷

As this commentator notes in his Ph.D. thesis: “The lack of homogeneity of approach to franchise specific laws between the different EU member states substantially dilutes its impact on cross border franchising. The lack of any uniform approach to pre-contractual disclosure further weakens the impact of franchise specific laws.”¹²⁸

It should not be concluded that the only obstacle presented to cross-border franchising by franchise-specific laws and regulations is their heterogeneity. Consider other recurring concerns:

- Requirements or prohibitions in some countries are sharply contradicted by requirements or prohibitions in other countries. “Earnings claims” or projections or estimates of likely sales revenues or profits are strictly regulated in the United States, and if proffered, are frequently the easiest target for a disappointed franchisee. By contrast, in the most recent South Korea amendments, franchisors are now required to provide information on projected sales revenue and the supporting materials for its projections, except for certain small franchisors.¹²⁹
- In the United States, it is uncommon to find a distribution arrangement that would be characterized as a “franchise” under one state statute but not under another, or be characterized differently under federal and state law. There are aberrations, to be sure (in New York, for example, if the “payment” prong of the definition is met but only one of the other two definitional prongs is present, it nonetheless constitutes a franchise).¹³⁰ But that is relatively rare and somewhat more common outside the United States. For example, consider France, where the description of the types of arrangements covered by *Loi Doubin* does not even use the term “franchising” or Russia, where it is viewed as a species of “commercial concession.”¹³¹ Thus, one cannot make a generalization about whether a particular distribution arrangement is covered by foreign laws with the same degree of confidence as in this country.

¹²⁷ Mark Abell, *Which EU Jurisdictions Most Heavily Regulate Franchising*, WHOSWHOLEGAL.COM (Nov. 2012), <http://whoswholegal.com/news/features/article/30097/which-eu-jurisdictions-heavily-regulate-franchising>.

¹²⁸ Mark Abell, *The Regulation of Franchising in the European Union* (July 4, 2011) (unpublished Ph.D. thesis, Queen Mary, University of London), available at <https://qmro.qmul.ac.uk/xmlui/handle/123456789/2326>.

¹²⁹ Philip Zeidman, *Collateral Damage*, FRANCHISETIMES.COM (Feb. 2014), <http://www.franchisetimes.com/February-2014/Collateral-Damage/>.

¹³⁰ N.Y. GEN. BUS. LAW § 681 (McKinney 2013).

¹³¹ Loi no 89-1008 du 31 décembre 1989 (Fr.), *supra* note 41; GRAZHDANSKII KODEKS ROSSIJSKOI FEDERATSII [GK RF] (Russ.), *supra* note 53.

- The consequences of violations of these laws are also less readily predictable than in the United States. Thus, the degree of severity a franchisor will confront has to be examined on a case-by-case basis. In some countries there is no governmental enforcement, leaving a dispute in the hands of the parties. In others, governmental authorities may respond to complaints by aggrieved parties;¹³² in Sweden that can even be an association of businesspeople.¹³³ In other countries, the government takes a more proactive role. In some cases, violations can constitute criminal offenses.¹³⁴
- One who seeks to engage in cross-border franchising may be forgiven for suspecting that in some countries the governmental intent is to make it as difficult as possible to engage in franchising in a rational fashion. In Indonesia, for example, it is very difficult, following termination or non-renewal of a franchise, to install a new franchisee without the concurrence of the former franchisee, who can block or delay the new registration.¹³⁵ The benign official description of this process as simply requiring a “clean break” obscures what it more nearly resembles: extortion.

X. Non Franchise-Specific Laws Which Impede Franchising

It would be a mistake for U.S. franchisors expanding internationally to assume that compliance with foreign franchise statutes completes their tasks, or their legal counselors. As in this country, the relationship between a franchisor and franchisee is governed by a far larger, broader, and older body of law; franchise statutes are a discrete, and typically more recent, addition to the legal disciplines which must be mastered.

Most of these other sources of limitation on the freedom of the parties are not peculiar to franchising; and, indeed, they will have no effect upon the parties beyond what they would have had on parties to non-franchising arrangements. For example, franchisors and non-franchisors alike will need to acquaint themselves with the differences between the common law to which they are accustomed in the United States and the civil law that may be applicable in a target country. Both will need to determine whether the parties may choose

¹³² For example, Belgium, Chile, El Salvador, France, Guatemala, Hungary, Netherlands, Philippines, Romania.

¹³³ Lag om franchisegivares informations skyldighet (Svensk författningssamling [SFS] 2006:484) (Swed.); *Medium-Small Retail Business Promotion Act*, 2009 Bus. Franchise Guide (CCH) ¶ 7158.

¹³⁴ See JAE HOON KIM AND SUN CHANG LEE, *Korea* in GETTING THE DEAL THROUGH: FRANCHISE 2014 (2013) (noting that in South Korea, in the event that a franchisor violates certain provisions of the Korea Franchise Act relating to disclosure requirements, the Korea Fair Trade Commission may file a criminal complaint with the attorney general); René Gelman and Rodrigo d'Avila Mariano, *Brazil*, Getting the Deal Through 2014 (noting that, in Brazil if a franchisor provides false information to franchisees, there may be criminal sanctions).

¹³⁵ Government Regulation on Franchise No. 16/1997 (Indon.), *supra* note 56; 2009 Bus. Franchise Guide (CCH) ¶ 7145 *supra* note 56.

as governing law the law of a jurisdiction other than that of the non-U.S. party—for example, the law of a state of the United States (although that may not always be the wise choice, as the U.S. party may assume, and even if, in theory, the law is enforceable, there are exceptions for provisions which run afoul of the public policy of the target jurisdiction). Contracting parties will need to determine whether the documents, especially any that must be registered with a government agency, must be translated. A franchisor is thus, for some purposes, no different than a non-franchisor.

But there are numerous legal structures—some statutory, some emanating from regulatory agencies, some arising from judicial decisions—which, although not enacted or adopted with franchising in mind, will nonetheless have an impact on franchising that can be significant, perhaps more so than in other contractual arrangements and documents.

An obvious, and threshold, example is that of intellectual property, especially trademarks. Since every franchise agreement is, at its heart, a license of a trademark and perhaps of other rights, nothing is as critical to the capacity of a franchisor to enter a foreign market as the clear right to protect its marks and other intellectual property. Since that right may not be certain in some jurisdictions, and since there may be technical procedural requirements that must be followed strictly, many franchisors have found their plans frustrated or delayed.

Another threshold consideration is the understanding in the legal jurisdiction as to the relationship between the parties. Franchisors operating in the United States have long learned to structure their relationships with their franchisees, where possible, in order to avoid characterization of their franchisees (or their franchisees' employees) as their agents or their employees and to conduct their relationship so as to avoid direct or vicarious liability for the acts of omission or commission of their franchisees. But “commercial agency” doctrines in several countries may complicate matters, with potentially severe consequences. In large parts of the Middle East, Latin America, and elsewhere, the characterization of a franchise arrangement, directly or by analogy, as a commercial agency can lead to such results as compensation—frequently, generous compensation—upon termination of the agreement, implied grants of exclusivity, and other consequences which can seriously impede a franchisor's marketing plans.¹³⁶ Avoiding that characterization, if achievable, will entail careful drafting and sometimes the cooperation of the franchisee.

A body of law which long precedes franchising, and in which the statutes were enacted and the judicial decisions rendered without regard to the then unknown “franchising,” is competition law. But that body of law, especially those aspects that deal with vertical relationships, can have a profound impact on franchising. That should hardly be surprising to U.S. franchisors, since most state statutes in this country dealing with the relationship between the franchisor and franchisee were directly or indirectly the product of

¹³⁶ See Cherry J. Hearn, Michael E. Santa Maria & Herbert S. Wolfson, Int'l Franchise Ass'n 47th Annual Legal Symposium: International Agency Laws: Ignorance is Not Bliss (May 6, 2014) (paper available at <http://emarket.franchise.org/d/2014-legal-attendees/International%20Agency%20Laws.pdf>).

traditional antitrust doctrines, and most early judicial decisions in this area arose from antitrust concepts. A useful example is that of covenants against competition, both during the term of the franchise agreement and after its expiration or termination. U.S. franchisors will find that the law of virtually every other country addresses covenants against competition, explicitly or implicitly and that the selection of the franchisor's home country's law is likely to be unavailing in the face of the target country's contrary public policy. Numerous other features of the franchise relationship, while unlikely to be addressed in the target country's franchise statutes, are almost certain to be dealt with in its competition laws. Common examples include a wide range of restraints of trade, including tying, full line forcing, retail price maintenance, price discrimination, and territorial and customer restrictions.

Tax considerations, currency restrictions, and exchange controls are important to every company, franchised or otherwise, seeking to do business in another country. Since virtually every franchisor depends upon royalties or other charges it repatriates to its home country, these considerations are central to the franchisor's choice of target market and the structure of its agreements.

The areas of law on which we have touched all fall loosely in the category of "non franchise-specific regulation that nonetheless affects franchising, sometimes differentially." In addition, of course, the principle of "good faith and fair dealing," or a variant thereof, is familiar to U.S. franchisors. But, because it will appear prominently in the other articles submitted for this Symposium, this Article will not be extended to treat that subject, except to note that, while that doctrine may or may not be applicable in the United States (depending upon applicable state law), it is very commonly found in many foreign jurisdictions, in some cases by statute.¹³⁷ U.S. franchisors will need to adapt their agreements—and, more importantly, their practices—to that reality.

But some statutory requirements are even "closer to the bone" than pure franchise laws. Some examples include:

- In the United States, with very few exceptions, federal and state statutes have definitions of "franchise," i.e. the conditions that determine whether an arrangement is covered by a statute, which are largely equivalent to one another. But in some foreign jurisdictions a contractual arrangement that avoids the definitional coverage in the United States (sometimes having been drafted to achieve that result) may nonetheless be within the reach of the operative franchise statute. Thus, in Mexico, the definition of "franchise" does not include the "fee" or "required payment" element universal-

¹³⁷ See Mark Abell, Marco Hero & R. Scott Toop, Int'l Franchise Ass'n 45th Annual Legal Symposium: Advanced Best Practices for International Regulatory Compliance (May 21, 2012) (paper available at http://www.franchise.org/uploadedFiles/IFA_Events/SecondaryPages/Advanced_best_practices.pdf).

ly required in the United States, and there are other such deviations around the world.¹³⁸

- Franchisors in the United States are accustomed to thinking of their offerings as products or services, but not “technology,” except in the broadest sense of that concept, and with no “franchise law” consequences flowing from that terminology if it appears in the franchise agreement. But in some countries, statutes dealing with transfers of technology contain provisions such as governmental discretion to disapprove certain contractual provisions, which may be broad enough to sweep in franchise agreements.¹³⁹ The technology transfer provisions in the Philippines’ Commercial Code, for example, have forced most foreign franchisors to accept provisions unfavorable to them (e.g., local law as governing law, compensation for derivative intellectual property developed by the franchisee, etc.).¹⁴⁰
- It is natural to assume that the “disclosure” statutes were adopted because, in their absence, the franchisor would have no legal obligation to make pre-contractual disclosures to a prospective franchisee. But that is not true in all jurisdictions. There may be an equivalent obligation, even in the absence of a franchise statute. In Germany, for example, a country with no statutory franchise disclosure law, well-advised franchisors nonetheless expressly disclose to their potential partners, in writing, all information deemed to be necessary by decisions of the German courts, which roughly track the disclosures explicitly required by countries with franchise disclosure statutes.¹⁴¹ Failure to do so can result in liability on the part of the franchisor.¹⁴²

XI. Prerequisites to Franchising; Other Sources of Complexity in the Statutes

Unlike the typical situation in the United States, there is an additional overlay of government activity that exists under the franchise laws of some countries. It is not entirely true that nothing of this sort exists in the United States. Here, under some state laws, the regulators are given the authority to refuse to register a franchise organization if they conclude that the franchisor does not have sufficient net worth or its financial outlook is not

¹³⁸ See Philip Zeidman, *Just like Home?*, FRANCHISETIMES.COM (Jan. 2014), <http://www.franchisetimes.com/January-2014/Just-like-Home/>.

¹³⁹ See e.g., INTELLECTUAL PROPERTY CODE, 1997 Rep. Act. No. 8293 (Phil.).

¹⁴⁰ *Id.*

¹⁴¹ Landgericht Kaiserslautern, Aktenzeichen 4 O 607/00 (2004).

¹⁴² See Philip Zeidman, *Hot Pursuit*, FRANCHISETIMES.COM, (June-July 2013), <http://www.franchisetimes.com/June-July-2013/Hot-Pursuit>.

stable.¹⁴³ In those situations the regulators can require that the franchisor place the initial fees paid by the franchisees into an escrow account, defer the collection of the initial fees until the franchised businesses are open, or purchase a bond assuring delivery of services for the initial fees paid.¹⁴⁴ But, as we shall see later, the preconditions in some foreign countries are considerably more intrusive.

The pace of change is accelerating. The number of proposals of new laws or of changes in existing laws is proliferating. Outside the United States, we confront a continuing movement of legislative and regulatory proposals, all against a complicating backdrop of language issues and delay in receiving information. Consider, for example, Indonesia. There, a proposal first advanced earlier would prohibit company-owned outlets, apparently prohibit area development arrangements, require the use of master franchise agreements, and require that there be multiple such arrangements¹⁴⁵—all apparently under the misguided belief that opportunities for independent businesspeople would thus be increased.

But perhaps the most confounding and in some sense pernicious development in the international regulation of franchising arises from a series of economic, political, and social developments in a number of countries in which franchising is simply “collateral damage.”¹⁴⁶ I refer to the growing trend in foreign franchise laws of requirements or obligations, which can only be characterized as tools for “social engineering.” By that I mean efforts by a government to limit the freedom of action of franchisors in such a way as to achieve certain social, political, or economic objectives, but which have no particular relationship to franchising at all.

I do not suggest that this is exclusively a “foreign” phenomenon. In the United States, too, governmental laws require, for example, that government contractors “set aside” a certain percentage of contracts for small businesses, disadvantaged people, or economic development of a disadvantaged area.¹⁴⁷ But these are in general limited to matters in which

¹⁴³ See BYRON E. FOX & BRUCE S. SCHAEFFER, FRANCHISE REGULATION AND DAMAGES §2.02 (2005). (discussing various state laws and procedures by which a state examiner may determine that the franchisor has inadequate funding, and therefore require the franchisor to comply with bonding or escrow procedures.)

¹⁴⁴ For example, see MD. CODE REGS. 02.02.08.08 (2014) (“[a]t any time after the submission of a registration statement and upon a finding that it is necessary and appropriate for the protection of prospective franchisees or subfranchisors, the Commissioner may require a franchisor to escrow franchise fees and other funds paid by a franchisee or subfranchisor until the franchisor’s obligations under the offering have been satisfied”); 21 VA. ADMIN. CODE § 5-110-65 (2014) (“[t]he commission may require a franchisor to escrow franchise fees and other payments made by a franchisee to the franchisor until the franchisor’s pre-opening obligations under the franchise agreement have been satisfied”).

¹⁴⁵ Ministry of Trade Regulations no. 53/M-DAG/PER/8/2012 (2012) (Indon.); Ministry of Trade Regulation no. 68/M-DAG/PER/10/2012 (2012) (Indon.); Ministry of Trade Regulation no. 07/M-DAG/PER/2/2013 (2013) (Indon.).

¹⁴⁶ See Zeidman, *supra* note 129.

¹⁴⁷ E.g., *Local Assistance-Women’s Business Centers*, SMALL BUSINESS ADMINISTRATION (last accessed July 28, 2014), <http://www.sba.gov/tools/local-assistance/wbc>.

there is a nexus with the government itself. Outside this country, however, we are beginning to see steps being taken to impose requirements on franchisors even when the government itself has no connection to the property or to the business.

Again, this is not entirely new. Governments have certainly imposed requirements upon companies that seek approval to franchise in a country. For example, some governments have expressly or otherwise imposed the requirement that an entering franchisor create a certain number of jobs in the process. But most “prerequisite” obligations can in theory be justified as being designed to protect the interests of prospective franchisees. For example, the requirements, which will be discussed later, that franchisors have engaged in the business for a certain period of time, in a certain geographic area, or with a certain number of units (some of which may be required to have been company owned) are all sought to be justified on the grounds that this is a way of demonstrating to a prospective franchisee that the franchisor is, by virtue of resources or experience, capable of discharging its obligations under a franchise agreement.

But in recent years we have seen governments going much further. Most of these steps can be seen as acting out of a desire to protect certain classes of people, to preserve certain industries or certain ways of life, or to prevent what is viewed as excessive economic concentration. A few examples:

- Malaysia requires that a certain percentage of franchises or subfranchises be reserved for Bumiputera, the descendants of native Malays.¹⁴⁸
- Indonesia requires that 80% of the sources of goods and services which a franchisor (or a franchisee) utilizes be from Indonesian sources.¹⁴⁹ Clearly this is not related to franchising but to a desire to protect local suppliers.
- Indonesia also requires that franchisors or master franchisees have no more than a certain number of units.¹⁵⁰ Again, there is no protection of franchisees entailed here; rather, the clear purpose is to require franchisors and master franchisees to distribute their franchises or subfranchises beyond powerful local interests to small and medium-sized businesses.
- South Korean regulations require that certain franchises not grow more than a certain number of units, or more than a certain percentage, per-

¹⁴⁸ Franchise (Amendment) Act 2012, Act A1442 (2012) (Malay.) Readers might query whether or not the requirements discussed in this section of the paper do not run afoul of the obligations pursuant to the World Trade Organization. See Philip Zeidman, *No Foreign Franchisors Need Apply*, FRANCHISING WORLD, Sept.-Oct. 1999, 43, 43; Philip Zeidman, *Social Engineering*, FRANCHISETIMES.COM (Sept. 2013), <http://www.franchisetimes.com/September-2013/Social-Engineering/>.

¹⁴⁹ See Philip Zeidman, *Paradise Lost?*, FRANCHISETIMES.COM (Nov.-Dec. 2012), <http://www.franchisetimes.com/November-December-2012/Paradise-Lost>.

¹⁵⁰ *Regulations—The Provisions on and Procedure for the Implementation of Franchised Business Registration*, 2009 Bus. Franchise Guide (CCH) ¶7145.

haps in a particular year.¹⁵¹ Again, the purpose is not to protect prospective franchisees but rather to prevent companies from growing to such a size that they drive local competitors out of business.

- South Korean law requires that a franchise not be built closer than a certain distance to an existing operation.¹⁵² While this may help some existing franchisees avoid competition, the purpose is probably not aimed at protection of franchisees but at protecting the existing businesses (probably small or medium sized and probably native).

Tunisian law requires that, in certain industries, franchising only be permitted with governmental approval.¹⁵³ Reports from Tunisian practitioners are that the Tunisian Ministry of Commerce may require, expressly or otherwise, assurances that prices will not be so low as to drive existing operations out of business, that there is a real need for an additional product or service of this nature, etc. The purpose, in other words, is not to protect prospective franchisees but rather to provide some assurance that permitting the entry of the foreign franchisor will not harm those who are already there; and, in particular industries, concerns which are clearly motivated by a desire to protect the existing companies. For example, the concern in the education field is apparently that the franchisees of foreign franchisors would intentionally fail an unwarranted number of students, simply to force them to come back and buy the course again.

XII. Is There a Way Forward?

A. Are These Impediments Evidence of Hostility to Franchising?

Should we then infer that governments are opposed to franchising? Curiously, the answer is almost certainly no. To the contrary, again and again we see governments' endorsement of franchising as beneficial, and worthy of support.

Even in the United States, which has historically been reluctant to devote governmental resources to support franchising, a new initiative by the Overseas Private Investment

¹⁵¹ See Philip Zeidman, *Social Engineering*, FRANCHISETIMES.COM (Sept. 2013), <http://www.franchisetimes.com/September-2013/Social-Engineering>.

¹⁵² On July 2, 2013, South Korea's National Assembly passed a partial amendment to the "Act on Fair Transactions in Franchise Business." Most of the amendments were effective six months after passage, although the effective date of these specific restrictions was deferred for a year to allow for compliance. See *Recent Developments in South Korean Franchise Law*, NEWSL. OF INT'L COMM'N TRANSACTIONS, FRANCHISING, & DISTRIBUTION COMM. (ABA Sect. of Int'l. Law, Chicago, IL), Fall 2013, at 19.

¹⁵³ In August 2010, the Government of Tunisia passed a law opening the Tunisian economy to foreign franchises in the sectors of retail/distribution, tourism, automobiles, and training. The government must approve franchising in other sectors, such as foodservice and real estate, on a case-by-case basis. See *U.S. Relations with Tunisia*, U.S. DEP'T OF STATE (Aug. 22, 2013), <http://www.state.gov/r/pa/ei/bgn/5439.htm>.

Corporation will guarantee loans made to the franchisees of U.S. franchisors in Tunisia (or to their suppliers) or to Tunisian franchisors.¹⁵⁴

Tunisia itself, before the advent of the Arab Spring, had announced plans to encourage university graduates to expand a government-created “Travel Shop” concept through franchising. In the Philippines, an exhortation went out to overseas Filipino workers to return home and channel their funds to franchise businesses.¹⁵⁵ In Malaysia, the government has identified franchising as a catalyst for entrepreneurs and devoted substantial resources to that end.¹⁵⁶ In Singapore, officials have established an explicit goal of making the nation-state the “franchising and licensing hub of Asia” and involved themselves directly in that process in a range of ways.¹⁵⁷ In Thailand, plans have been announced to establish a national franchise for the export of Thai products.¹⁵⁸

The list goes on: The Social Entrepreneurial Fund in Scotland;¹⁵⁹ the National Franchise Centre in Ireland, with training and financing;¹⁶⁰ franchise-specific lending programs in Australian banks¹⁶¹ and elsewhere, including the United Kingdom, Japan and the Philippines.

Taken together, this is a stunning picture of governmental support or promotion of franchising. And there are other green shoots. In the U.K., a recent study makes a forceful argument for further governmental support, especially for the exporting of British franchise systems.¹⁶²

One of the most interesting developments is in India. The movement toward energy reform (sorely needed, as any visitor to that country can attest) has led to the creation of franchises at the local level, with responsibilities for such hands-on functions as meter-reading, billing, revenue collection, theft control, and the like (strikingly similar to an approach proposed in

¹⁵⁴ U.S. Government Assistance to Tunisia, U.S. DEP’T OF STATE (Dec. 14, 2012), <http://www.state.gov/s/d/met/releases/198355.htm>.

¹⁵⁵ Michelle V. Remo, *DBP Sets Up Credit Facility for Overseas Filipino Workers*, PHIL. DAILY INQUIRER (June 29, 2011), <http://business.inquirer.net/5527/dbp-sets-up-credit-facility-for-overseas-filipino-workers>.

¹⁵⁶ See *Developing Franchises in Malaysia*, MINISTRY OF DOMESTIC TRADE, CO-OPERATIVES & CONSUMERISM, <http://www.kpdnkk.gov.my/en/pipfn-bantu-bangunan-industri-francais-malaysia> (last visited June 1, 2014) (describing Malaysia’s National Franchise Development Master Plan (PIPFN)); see also *Background*, PERBADANAN NASIONAL BERHAD, <http://www.pns.com.my/web/guest/about-us2> (last visited June 1, 2014).

¹⁵⁷ See *Local Enterprise and Association Development (LEAD) Programme*, SPRING SING. (Apr. 1, 2013), <http://www.spring.gov.sg/Industry/LEAD/Pages/local-enterprise-and-association-development.aspx> (describing Singapore’s Franchising and Licensing Association proposal).

¹⁵⁸ Somporn Thapanachai, *Upmarket Thailand Eateries Get State Support*, BANGKOK POST, Aug. 9, 2002.

¹⁵⁹ SOCIAL ENTREPRENEURS FUND, <http://www.scotland.gov.uk/Topics/People/15300/funding/Fund>.

¹⁶⁰ NATIONAL FRANCHISE CENTRE, <http://www.nationalfranchisecentre.ie/nfc.php>.

¹⁶¹ See NATIONAL FRANCHISE CENTRE, <http://www.nationalfranchisecentre.ie/index.php> (last visited June 1, 2014); *Social Entrepreneurs Fund*, SCOTTISH GOV’T (Apr. 13, 2012), <http://www.scotland.gov.uk/Topics/People/15300/funding/Fund> (describing the Scottish government’s fund). For examples of franchise specific bank websites, see, for example, COMMONWEALTH BANK OF AUSTRALIA, <https://www.commbank.com.au/corporate/industries/franchising.html> (last visited June 1, 2014) and NATIONAL AUSTRALIA BANK, <http://www.nab.com.au/business/industry/other-industries/franchising> (last visited June 1, 2014).

¹⁶² FRANCHISE DEV. SERV’S, THE UK FRANCHISE INDUSTRY RESEARCH REPORT 2013 (2013).

Brazil a decade ago).¹⁶³ The Indian twist suggests an approach we may see in other developing countries: The government has reached out to women-operated, self-help groups to take the lead in developing and operating these franchises.¹⁶⁴

Malaysia's Ministry of Domestic Trade is pressing hard to encourage young graduates to deviate from the traditional path of public sector jobs and turn instead to franchising, including toward some "micro-franchise" opportunities.¹⁶⁵ In Taiwan, the government is urging local franchise operations to expand more vigorously abroad, and there is some evidence this is occurring.¹⁶⁶

Perhaps most surprising of all, a North Korean food company which operates dozens of restaurants outside the country has started a website in its attempt to market franchises, traditional foods and crafts, and in the process, to earn hard currency for that cash-strapped society.¹⁶⁷ It is an open secret that the country's intelligence agency runs the effort.

This summary is not intended to suggest that this evidence of governmental support for franchising should be universally applauded. Indeed, it is often the precursor to intervention which, however well-intended, is frequently counter-productive. What it does demonstrate, though, is that this thicket of laws is not the product of some deep-seated suspicion of franchises.

B. Do These Impediments Argue for Abandonment of Plans for International Franchising?

But whatever their explanation, should we draw the conclusion that U.S. franchisors—and franchisors in other countries—should allow the disappointing legal landscape to dissuade them from venturing into otherwise attractive markets: That the deluge of national franchise laws, "with all good intentions," have so clouded the prospects for efficient and profitable cross-border franchising that franchisors should simply satisfy themselves with whatever they can wring out of an increasingly saturated domestic market?

¹⁶³ See GOV'T OF INDIA, MINISTRY OF POWER TRAINING MANUAL FOR NATIONAL FRANCHISEE TRAINING PROGRAM (NO DATE AVAILABLE), available at <http://recindia.nic.in/download/National%20Franchisee%20Training's%20Reading%20Material-English.pdf>.

¹⁶⁴ Dr. Rana Z. Masood, *Emergence of Women-Owned Businesses in India-An Insight*, II RESEARCHERS WORLD – JOURNAL OF ARTS SCIENCE & COMMERCE 233 (2011), available at http://www.researchersworld.com/vol2/PAPER_23.pdf; *Improving Access to Finance for Women-owned Businesses in India*, INTERNATIONAL FINANCE CORPORATION (last accessed July 29, 2014), <http://www.ifc.org/wps/wcm/connect/a17915804336f2c29b1dff384c61d9f7/Womenownedbusiness1.pdf?MOD=AJPERES; Women Entrepreneurship>, SMALL INDUSTRIES DEVELOPMENT BANK OF INDIA (last accessed July 29, 2014), <http://smallb.in/%20fund-your-business%20/additional-benefits-msmes%20/women-entrepreneurship>.

¹⁶⁵ See *Franchise Micro-financing Scheme*, PERBADANAN NASIONAL BERHAD, <http://www.pns.com.my/franchise-micro-financing-scheme> (last visited May 27, 2014) (describing "micro-franchising").

¹⁶⁶ Amy Su, *Chain Franchise Firms Eyeing World Market*, *TAIPEI TIMES* (April 5, 2013), <http://www.taipetimes.com/News/biz/archives/2013/04/05/2003558800>.

¹⁶⁷ Bill Gertz, *North Korea's Overseas Restaurants Used for Espionage and Gaining Hard Currency*, *WASH. FREE BEACON* (Oct 15, 2013), <http://freebeacon.com/north-koreas-overseas-restaurants-used-for-espionage-and-gaining-hard-currency>.

Hardly. After all, scores of U.S. franchisors are doing so successfully. McDonald's derives 68% of its revenues from outside the United States and YUM! derives 85%.¹⁶⁸

Those are, admittedly, the giants of franchising. But as we have seen, increasingly smaller companies, at earlier stages of their development, are making forays into international waters. And few of those companies are behemoths.

But what they will find is that, for the reasons we have examined, the process is longer, more difficult, and more expensive than it needs to be. The consequence is that fewer will go, to the detriment of franchisors and franchisees alike, to the competitive climate in the countries to which they would have otherwise ventured, and to the balance of payments in their home countries. And, of course, the needless impediments will lead to more failures, with the attendant human and material losses

Surely the answer is not—and the message of this Article is not—“make it like America.” The regulatory pattern in the United States has its own share of drawbacks. What works—tolerably—in America may not be appropriate for a different legal system and cultural context. And, more broadly, the world does not need more lectures from America. Is there, then, a sensible, achievable way to ameliorate a situation which threatens to hobble many putative international franchisors, so as not to deprive our globalized society of what has proven to be one of the most powerful marketing tools of our time? Let's examine some possible approaches.

C. Some Approaches to Examine

1. Uniformity

No one should reasonably anticipate true “conformity.” There are, after all, few aspects of human life in which there is universal agreement even on fundamental principles, and certainly not on their implementation. The sovereignty of individual countries renders that prospect even further beyond our reach.

But, even with that disclaimer, it should be apparent that one of the most disappointing aspects of the flood of regulation is how thoroughly it is characterized by disparities. Some of the requirements relate to obligations to make pre-sale disclosures. Some relate to limitations on the conduct of the franchisor. Some cover both. Some also impose obligations on the franchisee; some do not. Even in the area that would appear to lend itself most readily to uniformity, a list of subjects that the franchisor is required to disclose, there are extensive discrepancies. Some of the disclosures must be the subject of filing with a governmental agency; some need not. And the timing of such filings, and their consequences, differ considerably. In the “relationship” statutes the inconsistencies are even

¹⁶⁸ McDonald's Corp., Annual Report (Form 10-K) 9 (Feb. 25, 2013); Yum! Brands, Inc., Annual Report (Form 10-K) 90 (Feb. 20, 2013).

greater. And, as we have seen, even in the one region where one might have expected near-uniformity, the European Union, that is far from the case.¹⁶⁹

What does not seem unreasonable is for nations considering legislation to aspire to at least a rough approximation of what franchisors have come to expect elsewhere, to make an effort to eliminate deviations unless truly justified, and to be alert to “outlier” provisions or approaches which make compliance unduly difficult and render the market less attractive than others.

But the record of efforts to achieve a measure of uniformity is sparse and discouraging. One modest initiative to establish some common ground has made some headway: the effort to reach consensus on concepts and terminology. Beginning in 1985, a series of conferences and less formal conversations began to reveal that practitioners—often even in the same country and sometimes even in the same law firm—used different terms to refer to similar or even identical relationships, concepts, and legal structures. The negotiation of a cross-border contract sometimes more nearly resembled the construction of a Tower of Babel.¹⁷⁰

These discussions, under the aegis of both the International Bar Association and the International Franchise Association and initiated at an Annual Conference of the American Bar Association, led to *International Franchising: Commonly Used Terms*, published by the International Bar Association in 1989.¹⁷¹ Without purporting to be exhaustive, it made a useful contribution to progress in understanding this, then new, marketing and legal instrument, including a section entitled “Recommended Terminology.”¹⁷² But it is premature to claim success even by this modest standard: One continues to find laws, articles, and even legal agreements that utilize the same term to refer to different concepts or structures.¹⁷³ And it was always recognized that the report was only a beginning. It was subtitled “Volume 1”; no “Volume 2” ever followed.

A far more sweeping approach to “regularizing” international franchising was that initiated by UNIDROIT, the International Institute for the Unification of Private Law.¹⁷⁴ UNIDROIT, an independent, intergovernmental organization with offices in Rome, was originally established in 1926 as an auxiliary organ of the League of Nations.¹⁷⁵ Following

¹⁶⁹ See Mark Abell, *supra* note 128.

¹⁷⁰ The author participated in two such negotiations—one in Asia, one in Europe—which collapsed or were abandoned when, after days of intense and sincere exchanges, it was revealed that the parties had completely different understandings of a key concept.

¹⁷¹ ALEX S. KONIGSBERG, *INTERNATIONAL FRANCHISING: COMMONLY USED TERMS: VOLUME 1* (1989).

¹⁷² *Id.*

¹⁷³ See Philip Zeidman, *Still Babbling*, FRANCHISETIMES.COM (Aug. 2012), <http://www.franchisetimes.com/August-2012/Still-Babbling>.

¹⁷⁴ INT’L INST. FOR THE UNIFICATION OF PRIVATE LAW, MODEL FRANCHISE DISCLOSURE LAW (2002), available at <http://www.unidroit.org/english/modellaws/2002franchise/2002modellaw-e.pdf>.

¹⁷⁵ *History and Overview*, UNIDROIT.ORG, <http://www.unidroit.org/about-unidroit/overview>.

the dismantling of the League, it was re-established in 1940 on the basis of a multilateral agreement, the UNIDROIT statute.¹⁷⁶

The Secretariat of the organization proposed a project for preparation of a “model law on franchising” to its General Assembly.¹⁷⁷ Through a process of drafting committees, subcommittees, regular meetings, plenary sessions in Rome, and exchange of communications, and the delivery by a group of experienced franchisors, academicians, industry leaders, and observers of draft legislation presented to a committee of governmental experts; ultimately the Model Law was adopted in September 2002.¹⁷⁸

It is instructive to review the accompanying Explanatory Report, which candidly discusses the dispute that it sought to resolve:

The franchising community felt that the legislation that had been adopted in a number of countries risked severely hampering the development of franchising, and that therefore the adoption of similar legislation should if possible be avoided. If UNIDROIT prepared a model law, which by definition would be a balanced instrument considering the nature of the organization and the guarantees offered by its past history, legislators would have at their disposal an instrument that would promote and not hamper the development of franchising.¹⁷⁹

That lofty goal was what the organization aspired to produce, and by and large, the document itself succeeded. Even this ambitious effort must be recognized for the limited approach it embodies. Early in the discourse the drafters agreed that any attempt to produce a uniform law should be restricted to the pre-sale disclosure components, eschewing any effort to prescribe a universally applicable approach to “relationship” features, reporting that it had “arrived at the conclusion that the experience of States with relationship laws had been negative.”¹⁸⁰

Once the “model law” was adopted by UNIDROIT, there were high expectations that it would in fact be followed by those countries considering adopting franchise laws, and perhaps even cause those which had already enacted such laws to reconsider them. As one of the drafters (a Chair of the International Franchising Committee of the International Bar Association) wrote:

[The] Model Law should prove to be particularly useful as it would allow legislators to examine their own legal systems, the economic conditions, the standard of living, and the then current development of franchising within their own country, prior to adopting specific franchise legislation. Moreover, the Explanatory Report provides legislators with a detailed report of the entire process that went into the adoption of

¹⁷⁶ *Id.*

¹⁷⁷ INT’L INST. FOR THE UNIFICATION OF PRIVATE LAW *supra* note 174 at p. 14.

¹⁷⁸ INT’L INST. FOR THE UNIFICATION OF PRIVATE LAW *supra* note 174; *see generally* Philip Zeidman, *Ar-rividerci Roma*, FRANCHISE TIMES, June-July 2002, at 47; Philip Zeidman, *Unidroit: Approaching the Finish Line*, FRANCHISE TIMES, February 2001, at 46.

¹⁷⁹ LENA PETERS, INTERNATIONAL INSTITUTE FOR THE UNIFICATION OF PRIVATE LAW 49 (2011).

¹⁸⁰ INT’L INST. FOR THE UNIFICATION OF PRIVATE LAW, *supra* note 174.

the Model Law including an examination of provisions which were ultimately excluded from the Model Law, the reasons why particular provisions were excluded and the reason why other provisions were ultimately adopted. In addition, the Model Law brings issues to the attention of the legislators that should be taken into account prior to the adoption of specific franchise legislation.

As a result, countries which, prior to the adoption of the Model Law, had adopted their own franchise specific legislation, may give serious consideration to amending such legislation in accordance with the provisions of the Model Law and thereby avoid some of the more draconian and even negative provisions contained in such laws.¹⁸¹

Those expectations were not fulfilled. No laws were repealed, and law after law was adopted thereafter, with little, if any, evidence that the UNIDROIT formulation had served as a model. It has been translated into several languages but otherwise gathers dust in the headquarters of UNIDROIT, a reminder of the difficulties of such efforts.

One other such attempt should be noted. After a number of years of discussion the International Chamber of Commerce in 2011 published the *ICC Model International Franchising Contract*.¹⁸² The protracted delay was caused, in large measure, by the widely held view of franchise specialists that it was impractical to attempt to cast so wide a net, to cover so large a range of different business arrangements. Other criticisms prominently include the slant of the proposals to a European audience, to product distribution franchises rather than “uniform business format” arrangements, and to direct single unit agreements, rather than those more commonly used in cross-border transactions, master franchises or area development agreements.” Other criticisms were directed at some critical missing clauses, ambiguities, and unresolved open issues.

As widely predicted, the proposal has had negligible if any effect on the practice of cross-border franchising. It remains largely unused by—and unknown to—most franchisors.¹⁸³

One is impelled to the conclusion that localized, and sometimes idiosyncratic, approaches will not be abandoned and that their grip will not be loosened. The resistance to change by both governments and private practitioners, the determination not to have the views of “outsiders” imposed, was simply underestimated. We can no longer avoid the conclusion: uniformity will not be the solution.

¹⁸¹ ALEX S. KONIGSBERG, INTERNATIONAL FRANCHISING 63-64 (2008).

¹⁸² INT’L CHAMBER OF COMMERCE, ICC MODEL INTERNATIONAL FRANCHISING CONTRACT (2nd ed. 2011).

¹⁸³ See Philip Zeidman, *The Deceptive Appeal of ‘Standard’ Agreements*, FRANCISETIMES.COM (Sept. 2011), <http://www.franchisetimes.com/September-2011/The-deceptive-appeal-of-standard-agreements>.

2. Testing the Waters

Unless they are arrogant, careless, or foolish, when businesses venture into unfamiliar territory—whether with a new product or service, utilizing a new way of doing business, or entering a new country—they do so with great care and as much advance planning as is feasible and affordable. And, even with all that preparation, because they know they will encounter the unexpected, they try to limit their risk by limiting their commitment. If they find that any of the myriad unknowns—the competition, the sources for product, the culture—threaten to render the venture unviable, they want to be able to cut their losses.

Franchising is no different. Franchisors want to be able to commit no more than necessary to a planned expansion—in terms of time, cost, and personnel—until they can make an informed assessment of the prospect for success.

But one of the more frustrating impediments to international franchising arises at the very outset of a company’s consideration of embarking on a cross-border strategy. Prudent businesspeople recognize that what works at home may not work elsewhere, or at least not without substantial adaptation, and that what works in one market may not in another. They would like to do abroad what they wisely do at home: “test the waters” in a new market.

The franchise laws make that practically impossible. The heavily front-loaded process of international franchise expansion and compliance requires a franchisor to take all the steps required to franchise, with the attendant costs, even if the transaction contemplates only a single unit in a single foreign country. Since that is virtually never an economically viable step, many franchisors either (a) decide not to go forward; (b) opt not to comply with the laws; or (c) enter into a transaction which entails a greater commitment than can be justified, simply because the cost of doing so differs little from a much smaller transaction. The franchise laws thus act to nudge franchisors toward non-economic decisions, with predictable consequences, or to violate the laws.

Responding to the difficulties this imposes, some jurisdictions have sought to alleviate the burden. The concept of an “isolated sale” exemption is one such response: In New York, a franchisor can avoid the obligation to register its franchise offer with the state if it is selling only a single franchise (a way of testing the waters).¹⁸⁴ But this exemption does not shield the franchisor from the requirement to produce a disclosure document and deliver it to a prospective franchisee.¹⁸⁵ A similar limited exemption exists elsewhere, for example, in Minnesota.¹⁸⁶ In addition, court decisions have expanded certain state laws’ definitions of

¹⁸⁴ NY GEN. BUS. LAW § 684(3)(c) (McKinney 2012).

¹⁸⁵ *Id.*

¹⁸⁶ MINN. STAT. § 80C.03(e)(1) (2013).

“good cause” to include “withdrawal from the market,” permitting termination of franchisees in such circumstances.¹⁸⁷

So strong is the prohibition against testing the waters that some jurisdictions will not permit a company to franchise until it has first entered the country with company-owned units, sometimes more than one, and in some cases has operated them for a minimum period of time.

Variations of this approach exist in certain countries. In Vietnam, a franchisor’s system must have been in operation for at least a year before a franchise can be granted, and the same requirement is imposed on a Vietnamese subfranchisor before it can grant subfranchises.¹⁸⁸ China requires a franchisor to establish and operate at least two company-owned units for at least one year before it grants franchises; the earlier regulation specified that the pilot organizations be in China, but the current law has removed that requirement.¹⁸⁹ Since this increases the amount of capital that must be committed, as a practical matter, it bars all but well capitalized companies. Indeed, it can bar even some very large companies whose business model calls for an entirely franchised network.

Testing the waters or establishing a “pilot operation” is, in theory, a manageable way to determine, in an affordable fashion, whether a small or medium sized franchisor can sensibly undertake a venture into the swamp of international regulation. In practice, given the state of the franchise laws and the cost of both entry and compliance, it simply will not work.

3. Protecting Only Those Who Need Protection

It seems self-evident that the heavy artillery of government should not be wheeled into place to protect franchisees or prospective franchisees unless they are truly in need of protection. Otherwise, a waste of government resources and unnecessary and costly behavior by franchisors will be triggered, despite the absence of any demonstrable need.

Several franchise statutes or regulations have sought to strike a sensible balance, targeting those in need of protection by excluding those who are not. Thus, the UNIDROIT Model Franchise Disclosure Law excludes from protection, among others, a franchisee of substance, who either commits to a total financial requirement in excess of an amount to be specified or who, together with its affiliates, has a net worth or turnover in excess of an amount to be specified.¹⁹⁰ The purpose is to relieve the franchisor of the cost, time, and burden of compliance when there is reason to conclude that the franchisee is “a person of

¹⁸⁷ See, e.g., WIS. STAT ch. 135; see, e.g., *Lee Beverage Co., Inc. v. I.S.C. Wines of California, Inc.*, 623 F. Supp. 867 (E.D. Wis. 1985); see, e.g., *St. Joseph Equip. v. Massey-Ferguson, Inc.*, 546 F. Supp. 1245 (W.D. Wis. 1982).

¹⁸⁸ Decree no. 35-2006-ND-CP of March 31, 2006 (Viet.); *Franchising Regulations*, 2009 Bus. Franchise Guide (CCH) ¶ 7282.

¹⁸⁹ *Introduction—China*, 2009 Bus. Franchise Guide (CCH) ¶ 7060 (discussing 2007 regulations).

¹⁹⁰ INT’L INST. FOR THE UNIFICATION OF PRIVATE LAW *supra* note 174.

such level of sophistication and knowledge that he/she has access to the advice of legal counsel” or “who by virtue of his/her net worth or turnover is assumed to have such a level of sophistication and prior business experiences,” and thus that “he/she does not require the protection of this law.”¹⁹¹ This is similar to the theory of exempting “accredited investors” from certain aspects of the protection of the securities law, using income and net worth as an admittedly arbitrary proxy for sophistication and experience.¹⁹²

But this approach has found little support. The FTC Rule (which preceded the UNIDROIT formulation), from the outset, contained two exemptions for circumstances in which it was concluded that there was inadequate evidence that a prospective franchisee required the protection of disclosure: (a) a very minimal investment and (b) a “fractional franchise” (defined as when the franchisee or its principals have had at least a specified minimum period of prior experience in the same type of business and the parties anticipate that the sales from the proposed relationship will represent no more than a specified percentage of the dollar volume of the franchisee’s total projected gross sales for an initial period of time).¹⁹³ Most of the states with franchise registration and disclosure laws have enacted fractional franchise exemptions, but the exemptions vary from state to state and may require the payment of a filing fee and/or the submission of an exemption notice.¹⁹⁴ More recently, the FTC expanded this effort to narrow the protection of the FTC Rule to those deemed in most need of it, exempting very large investments and franchisees with large net worth.¹⁹⁵ Several of the states with franchise registration and disclosure laws have exemptions for large franchisees (meeting certain minimum net worth and/or experience requirements) and/or large investments (meeting a threshold level of investment in the franchise), but some of the exemptions provide an exemption only from registration, not from disclosure.¹⁹⁶

Jurisdictions outside the United States have, by and large, not welcomed such initiatives. Australia and certain Canadian provinces have adopted a version of the fractional franchise exemption. But no other countries have followed the approach, and with the exception of certain Canadian provinces, none appear to have adopted the large investment or sophisticated/large net worth exemptions.

¹⁹¹ *Id.* § 74.

¹⁹² See 15 U.S.C. § 77d (2014); see 17 C.F.R. §§ 230.501-230.508.

¹⁹³ Promulgation of Trade Regulation Rule and Statement of Basis and Purpose, 43 Fed. Reg. 59,614, 59,735-36 (Dec. 21, 1978) (to be codified at 16 C.F.R. pt. 436).

¹⁹⁴ See generally *State Exemptions from Disclosure Requirements and State Exemptions from Registration Requirements*, 2009 Bus Franchise Guide (CCH) ¶ 390 et. seq., 430 et. seq. (discussing state exemptions, and noting that fractional sales exemptions are available in California, Illinois, Indiana, Michigan, Minnesota, South Dakota, and Wisconsin.)

¹⁹⁵ Disclosure Requirements and Prohibitions Concerning Franchising – Exemptions, 16 C.F.R. 436.8(a)(5)(i)-(ii) (2012).

¹⁹⁶ See *State Exemptions from Disclosure Requirements and State Exemptions from Registration Requirements*, 2009 Bus Franchise Guide (CCH) supra note 198 (noting that some versions of experienced/large/ seasoned franchisor exemption(s) are available in California, Illinois, Indiana, New York, North Dakota, Rhode Island, Virginia, and Washington.)

Exemptions and exclusions seem an eminently sensible way to narrow the target of franchise laws to those to whom they should be directed. Unfortunately, far too few countries have taken this commonsense approach, and I believe we must, regretfully, conclude that it is too late to reconfigure the landscape in this fashion.

4. Back to First Principles

It is unrealistic to expect to be able to roll back the clock in countries that have enacted such legislation. The psychic and political investment in placing the laws on the books has simply been too great, and the openness to repeal them is simply not to be found.

But what of the rest of the world, those countries where no such legislation exists? What can be done in those countries, once there is an indication that legislation may be contemplated?

The answer, in my judgment, lies in a commitment to educate legislators, government officials, and industry itself of some straightforward principles, urged by UNIDROIT itself, in the form of questions that legislators should pursue. As UNIDROIT articulated, the standard that legislators should demand be met:¹⁹⁷

- whether it is clear that there is a problem, what its nature is, and what action, if any, is necessary;
- whether prospective investors are more likely to protect themselves against fraud if they have access to truthful, important information in advance of their assent to any franchise agreement;
- whether the nation's economic and social interests are best served by legally requiring a balance of information between the parties to a franchise agreement;
- whether there is a pattern of abusive conduct, or whether this conduct is isolated or limited to particular industries;
- the nature of the evidence of abuse;
- whether existing laws address the concerns and whether they are adequately applied;
- whether an effective system of self-regulation exists;
- the financial burden the new legislation will place upon franchisors and investors as compared to the benefits of legally required disclosure; and
- whether the proposed legislation inhibits or facilitates entry to franchisors, and its effect on job-creation and investment.

These seem self-evident. Yet experience has shown that few legislators are prepared to undertake a rigorous inquiry of this nature.

¹⁹⁷ INT'L INST. FOR THE UNIFICATION OF PRIVATE LAW, *supra* note 174, at 1.

Persuading them to do so is today's challenge to the international franchising community and to its legal advisors. We may not be able to make the world a better place to do business. But perhaps we can prevent it from becoming worse.

MEMORANDUM

From: Joseph A. Levitt
Elizabeth Barr Fawell

Date: September 30, 2014

Re: FDA Issues Supplemental Foreign Supplier Verification Program Proposed Rule Under FSMA

On Friday, September 19th, the Food and Drug Administration (FDA) released four supplemental notices of proposed rulemaking, proposing changes to the following rules first proposed in 2013 to implement the FDA Food Safety Modernization Act (FSMA): Preventive Controls for Human Food; Preventive Controls for Animal Food; Foreign Supplier Verification Program (FSVP); and Produce Safety. This memorandum provides key takeaways and highlights of the major provisions from the supplemental proposed rule for FSVP. ^{1/} FDA will accept comments on the revised FSVP provisions until December 15, 2014, while continuing to review comments already received on the original proposed rule. FDA will not accept additional comments on the original proposal.

Overview

The proposed revisions to the FSVP rule primarily address compliance status review of food and foreign suppliers, hazard analysis, and supplier verification activities, and would make the regulations more flexible and risk-based. These changes are based on input from stakeholders in response to the proposed rule and demonstrate the significant effect that public comments can have on the rulemaking process. FDA's revisions are directly responsive to many of the requests from the food industry. Importantly, the FSVP supplemental rule closely tracks the supplier verification program in the supplemental proposed rule for preventive controls issued concurrently by the agency.

It is important to keep in mind, however, that FDA has not completely re-proposed the FSVP rule. Although the supplemental proposal addresses major components of the 2013 proposed rule, it does not address all of the issues on which stakeholders commented. For example, FDA does not address the definition of "importer" or whether to provide an exemption for intra-company shipments. The agency will not accept additional comments on these issues, but will continue to review comments already submitted on the original proposed rule. These issues, as well as new issues raised by the supplemental proposed rule, will be resolved in the final rule. As a reminder, by court order the FSVP final rule must be issued by October 31, 2015.

^{1/} See HL Memorandum, *FDA Issues Supplemental Preventive Controls Rules Under FSMA* (Sept. 26, 2014); HL Memorandum, *FDA Re-Issues Key Section of Produce Safety Proposed Rule Under FSMA* (Sept. 26, 2014).

Summary of Key Revisions

- Consideration of Supplier Risks. In response to numerous industry comments stating that industry best practice is to base supplier verification activities on an assessment of information about the risks presented by the supplier as well as risks presented by the food, FDA proposes two significant changes to the original proposed rule. First, FDA proposes to delete the previously proposed section on compliance status review. Second, FDA proposes to create a new provision on “risk evaluation,” which would specify that, along with the hazard analysis (which would assess risks associated with the food) the importer must consider factors primarily related to supplier risks in determining appropriate supplier verification and related activities. Thus, FDA agrees with industry that the scope of supplier verification should include supplier risks, rather than focus primarily on hazards inherent in food.
- Appropriate Verification Activities: FDA proposes to give importers the flexibility to determine appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods. Under the revised proposal, based on the risk evaluation the importer conducts, the importer would be required to determine and document what supplier verification activities are appropriate for a particular food and foreign supplier, as well as the frequency with which those activities should be conducted. However, the revised proposal also specifies that, when there is a hazard in a food that could result in serious adverse health consequences or death to humans or animals (a “SAHCODHA” hazard), an importer would need to conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless the importer specifically determined that some other supplier verification activity and/or less frequent auditing would adequately address the identified risks.
- Confidentiality of Audit Reports: In response to industry comments, FDA is proposing not to require FDA access to audit reports of suppliers, but instead to accept documentation regarding the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.
- Approved Supplier List: Instead of requiring importers to maintain a list of their foreign suppliers, under the supplemental proposal importers would be required to establish and follow procedures to ensure they import foods only from foreign suppliers that they have approved (except, when necessary and appropriate, from unapproved suppliers on a temporary basis).
- Deemed Compliance: FDA is proposing to add provisions stating that when importers or their customers are in compliance with the requirements on supplier verification programs in the proposed preventive controls regulations, the importers would be deemed in compliance with most of the FSVP requirements.
- Very Small Importer/Supplier: FDA proposes to increase, from \$500,000 to \$1 million, the annual sales ceiling used in the proposed definition of “very small importer” and “very small foreign supplier” to be consistent with the revised approach to the proposed definition of “very small business” under the proposed preventive controls regulations.

Additional details on these issues as well as other changes to the proposed rule are contained in the attachment to this memorandum. In addition, FDA has published a redline version of the proposed FSVP regulations in the docket on regulations.gov.

* * *

We will continue to closely monitor all developments related to FDA's implementation of FSMA. If you have any questions regarding the supplemental proposed rules, please do not hesitate to contact us.

ATTACHMENT

Summary of Proposed Revisions from the FSVP Proposed Rule

Purpose of Supplier Verification:

FDA is proposing that, rather than being designed to ensure that identified hazards are adequately controlled, the purpose of an importer's supplier verification activities should be to provide adequate assurances that the foreign supplier produces the food in a manner consistent with FDA's regulations on preventive controls or produce safety, if either is applicable to the foreign supplier, and to assure that the food is not adulterated and not misbranded regarding allergen labeling. This change is intended to more closely align the regulations with the statutory provision.

Hazard Analysis:

Under the revised proposal, the importer would be required to conduct a hazard analysis for each food imported. Like the preventive controls supplemental proposed rule, the importer would evaluate known and reasonably foreseeable hazards to determine whether there are any significant hazards. ^{2/} Also consistent with the preventive controls supplemental proposal, the hazard analysis would need to consider any hazards that may be intentionally introduced for purposes of economic gain, as well as an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the food does not receive a treatment that would significantly minimize the pathogen. The hazard analysis would be written.

The importer would be able to meet its requirement to determine whether there are any significant hazards by reviewing and assessing the hazard analysis conducted by the foreign supplier. If the importer determined that there are no significant hazards in the food (either through its own hazard analysis or by reviewing and assessing the analysis conducted by its supplier), it would not be required to determine or conduct supplier verification activities.

Further, if the preventive controls that either the importer or its customer implement are adequate to significantly minimize or prevent all significant hazards in the imported food, the importer would not be required to determine or conduct any foreign supplier verification activities. However, if the importer's customer controls the significant hazards, the importer would be required to annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

Risk Evaluation:

FDA is proposing to add a new provision on "risk evaluation." The risk evaluation would determine the appropriate supplier verification and related activities. Whereas the hazard analysis would focus on the risk of the food, the risk evaluation would consider both the hazard analysis and supplier related risks. Specifically, the risk evaluation would consider the hazard analysis, as well as:

^{2/} Importers would not be required to determine whether there are any significant microbiological hazards in raw agricultural commodities that are fruits or vegetables, as FDA has already made that determination on a commodity-wide basis.

- The entity that will be applying controls for the hazards analyzed under the hazard analysis, such as the foreign supplier or the foreign supplier's raw material or ingredient supplier.
- The foreign supplier's procedures, processes, and practices related to the safety of the food.
- Applicable FDA food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert.
- The foreign supplier's food safety performance history, including results from testing foods for hazards, audit results relating to the safety of the food, and the supplier's record of correcting problems.
- Any other factors as appropriate and necessary, such as storage and transportation practices.

The importer would be required to document each risk evaluation and promptly reevaluate the risk factors specified when it becomes aware of new information about these factors. If the importer determined that it was appropriate to continue to import the food from the foreign supplier, it would document such a determination and its reevaluation.

FDA intends to issue guidance on the specific information it believes should be considered under each of these factors and how these factors might be weighed in evaluating overall risk. The agency also intends to issue guidance on the circumstances under which importers should reevaluate food and supplier risks.

Foreign Supplier Verification Activities:

Importers would be required to establish and follow written procedures for conducting supplier verification activities. The specific verification activities, as well as their frequency, would be based on the risk evaluation. Both the nature of the verification activity and implementation of that activity would be documented. Importers would have the flexibility to choose the verification activities and appropriate verification activities would include onsite auditing, sampling and testing food, review of the foreign supplier's food safety records, or some other risk-based verification activity. Onsite audits would need to be conducted by a qualified auditor (who may be a foreign government employee) and sampling and testing could be conducted by either the importer or the foreign supplier.

With respect to hazards that pose a risk of serious adverse health consequences or death to humans or animals (SACODHA), FDA proposes a slightly different approach designed to strike a balance between granting importers flexibility to adopt risk-based verification measures while increasing the likelihood they will apply the most rigorous verification measures to the most serious risks. Thus, when there is a reasonable probability that exposure to the hazard will result in SAHCODHA, the regulations would require an initial onsite audit and annually thereafter, unless the importer documents its determination that other verification activities and/or less frequent audits provide adequate assurance that the hazards are controlled. ^{3/}

^{3/} FDA notes in the preamble that for onsite audits conducted for FSVP purposes, importers would not be required to obtain a regulatory audit report as required for audits conducted by

In the preamble, FDA explains that it does not believe that purported uncertainty about the SAH/CODHA standard would make it difficult for importers to comply with this provision and directs importers to the Reportable Food Registry Questions and Answers document as well as its weekly Enforcement Reports for guidance. In addition, FDA may consider providing additional guidance to help clarify what food hazards are SACODHA hazards under FSVP. FDA intends to provide guidance to industry on the circumstances (incorporating both food and supplier risks) under which onsite auditing of foreign suppliers and/or other supplier verification approaches are appropriate for providing adequate assurances regarding the safety of the food produced by a foreign supplier.

FDA proposes that instead of an onsite audit, an importer may rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. The importer would need to document the inspection results it relied upon.

If the foreign supplier is a farm that is not subject to produce safety requirements, the importer would not need to conduct and document verification activities if it documents that the food is not subject to the produce safety rule and obtains written assurance every two years that the supplier is producing food in compliance with Federal, Food, Drug, and Cosmetic Act. This provision would apply to foods such as grains, produce that is rarely consumed raw, or produce that is not a raw agricultural commodity.

Importers would need to review the results of verification activities and, if the results show that the risks for the food or the supplier are not adequately controlled, take corrective action.

List of Approved Suppliers:

Instead of maintaining a list of their foreign suppliers, under the revised proposal, importers would be required to establish and follow written procedures to ensure that they import foods only from foreign suppliers that they have approved (except, when necessary and appropriate, from unapproved suppliers on a temporary basis). Importers would be required to document use of these procedures, which might address approval of suppliers, approval or rejection of particular shipments of foods, and documentation of receipt from approved suppliers.

Reassessments:

The revised proposal would require an importer to promptly reassess the effectiveness of its FSVP for a food when it becomes aware of new information about potential risks associated with the food or foreign supplier of the food (instead of when the importer becomes aware of information about potential food hazards, as under the original proposed rule). The importer would update its risk evaluation and if the reassessment led to a change in the identified risks, it would need to determine whether it needed to change its verification activities. The importer would document each reassessment and any changes to its FSVP.

accredited auditors/certification bodies under FDA's proposed rule on "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications."

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Records and Documentation:

There are numerous documentation requirements in the supplemental proposed rule. For example, importers would need to document their hazard analysis and the risk evaluation (and reevaluation) and would need to establish written procedures for conducting supplier verification activities and for ensuring they only import food from approved suppliers. In addition, they would need to document which verification activity is appropriate and the frequency with which the activity must be conducted for the supplier and the food, implementation of that activity, and use of procedures established to ensure they only import food from approved suppliers.

FDA also proposes to establish minimum requirements for records documenting an audit, records of sampling and testing, and records documenting review of the supplier's relevant food safety records.

Audits. In the preamble, FDA acknowledges concerns about requiring importers to document onsite audits of foreign suppliers with full audit reports and states that the agency does not believe that importers should be required to make full audit reports available to the agency in a FSVP inspection. Under the revised proposed rule, the importer would be required to provide the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

Testing. Sampling and testing documentation would need to include the following: Identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical methods(s) used), the date(s) on which the test(s) were conducted, the results of the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing.

Review of foreign supplier safety records. Documentation of each review of foreign supplier safety records would need to include the date(s) of review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

Under the revised proposed rule, importers would be required to maintain for at least 2 years (after the records were created or obtained) records of, among other things, written assurances from their customers that they are in compliance with the supplier program requirements of the preventive controls regulations, certain verification activities, investigations and corrective actions, FSVP reassessments, and documentation of supplier verification activities that importers conduct.

Very Small Importer/Supplier:

FDA revises the proposed definitions of very small importer and very small foreign supplier by increasing the annual food sales ceiling from \$500,000 to \$1 million, consistent with the revised proposed definition of very small business set forth in the preventive controls supplemental proposed rule. FDA is still considering the comments it received concerning whether the regulations should include any such modified provisions for very small importers and suppliers and, if so, what the modified requirements should be, and whether the food sales to be considered for eligibility determinations should be limited to sales in or to the United States, rather than all food sales of an importer or foreign supplier.

Qualified Individuals

Under the original proposed rule, a qualified individual who conducts verification activities must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit the importer or one of its employees from conducting the verification activity. FDA is not proposing to revise this requirement, but requests comment on this provision and on additional conflict of interest issues such as whether such requirements should be directed at certain persons (e.g., auditors) and what should constitute a financial interest.

Dietary Supplements:

FDA proposes revising the modified FSVP requirements for importers of dietary supplements to reflect the other changes to the proposed rule. In the supplemental proposal, FDA continues to distinguish between whether the importer is bringing in dietary supplement components or dietary supplements that will be subject to further processing (including packaging and labeling); or “finished” dietary supplements. The revised proposed regulations would specify that importers of dietary supplements and dietary supplement components that will be further processed (and thus are subject to the dietary supplement GMP regulation in Part 111) would not be required to comply with the requirement to establish and follow written procedures to ensure the use of approved suppliers. The same would be true if the importer is not subject to Part 111, but its customer is. FDA states this change is appropriate because these importers would not be required to comply with most of the generally applicable FSVP requirements, including the requirement to conduct risk evaluations, which provide the basis for supplier approval.

FDA also proposes to revise several of the provisions regarding importers of dietary supplements that will not be further processed. The regulations would specify that although importers of these “finished” dietary supplements would not be required to analyze the hazards in the dietary supplements they import, they would be required to evaluate the other risks set forth in the risk evaluation provision (i.e., supplier risks). Further, importers of these dietary supplements would be required to establish and follow written procedures to ensure that foods are imported only from approved suppliers (except in the limited circumstances when unapproved suppliers may be used), rather than having to maintain a list of their foreign suppliers as was proposed in the original proposed rule. Importers of these products would need to conduct supplier verification and related activities.

MEMORANDUM

From: Joseph A. Levitt
Elizabeth Barr Fawell

Date: September 26, 2014

Re: **FDA Issues Supplemental Preventive Controls Proposed Rules Under FSMA**

On Friday, September 19th, the Food and Drug Administration (FDA) released four supplemental notices of proposed rulemaking, proposing changes to the following rules first proposed in 2013 to implement the FDA Food Safety Modernization Act (FSMA): Preventive Controls for Human Food, Preventive Controls for Animal Food, and Foreign Supplier Verification Program (FSVP); and Produce Safety. FDA will accept comments on the revised provisions for 75 days after publication in the Federal Register, while continuing to review comments already received on the original proposed rules. 1/ FDA will not accept additional comments on the original proposals.

This memorandum provides key takeaways and highlights of the major provisions from the supplemental proposed rule for preventive controls for human food and the supplemental proposed rule for preventive controls for animal food. We also are issuing today a separate memorandum on the produce safety supplemental proposed rule. We will then issue a memorandum on the supplemental proposed rule for FSVP. 2/

Overview

The proposed revisions to the preventive controls rules would make the regulations more flexible, practical, and targeted. These changes are based on input from stakeholders in response to the proposed rules and demonstrate the significant effect that public comments can have on the rulemaking process. FDA's revisions are directly responsive to many of the requests from the food industry and overall result in proposed requirements that are more flexible, risk-based, and tailored to the individual food facility. The proposed revisions are a significant improvement and provide the food industry with a clear indication of what the final requirements likely will look like when they are issued in 2015.

It is important to keep in mind, however, that FDA has not completely re-proposed the preventive controls rules. Although the supplemental proposals address major components of the 2013

1/ The supplemental proposed rules are expected to publish on Monday, September 29th, making the comment deadline approximately Monday, December 15, 2014.

2/ FDA's desire for consistency between FSVP and supplier verification requirements in the preventive controls supplemental proposed rules means that the summary provided below provides a preview of the requirements in the FSVP supplemental proposed rule.

proposed rules (such as the hazard analysis, the management of preventive controls, and testing and supplier verification as well as GMPs for animal food), they do not address all of the issues on which stakeholders commented. For example, FDA does not address consumer complaints, food safety plans for pilot plants, refrigerated warehouses, or compliance with Part 11 electronic recordkeeping requirements. The agency will not accept additional comments on these issues, but will continue to review comments already submitted to the original proposed rules. These issues, as well as new issues raised by the supplemental proposed rules, will be resolved in the final rules. As a reminder, by court order these final rules must be issued by August 30, 2015.

Below we outline some of the key revisions found in the supplemental notices. Because most human food companies do not intentionally produce animal food, though they may divert by-product or food processing waste, this memorandum focuses on the human food rule. Nonetheless, for the most part, the proposed rule regarding animal food is the same as the one for human food. Where there are key differences between the two rules, we note them.

Highlights of Key Revisions

1. Hazard Analysis:

FDA agrees with industry comments to delete the phrase “reasonably likely to occur” (RLTO) from the regulations. Industry had argued that RLTO has been used as the basis for determining hazards that need to be addressed at Critical Control Points (CCPs) in hazard analysis and critical control point (HACCP) systems and that preventive controls under FSMA are much broader than just CCPs. FDA agrees it could be confusing to have the same term in both the agency regulations for HACCP programs and the FSMA regulations when, indeed, preventive controls under FSMA are broader than CCPs under HACCP. In its place, FDA proposes to use the term “significant hazard.”

FDA would define “significant hazard” as a “known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would . . . establish controls to significantly minimize or prevent the hazard in a food and [would establish] components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.”

FDA also provides in the proposed codified language, in response to industry comments, that the hazard analysis would need to include an evaluation of both the “severity” and “probability” of the hazard. Note that FDA describes “probability” as meaning the likelihood the hazard would occur “in the absence of preventive controls.” FDA explains that, although the term “significant hazard” also has some association with CCPs, the agency believes that the proposed definition and other changes to the regulations make it clear that preventive controls are not limited to CCPs, nor do all necessary preventive controls need to be established at CCPs.

FDA also proposes to include a requirement to evaluate hazards that may be introduced as a result of economically motivated adulteration (see below) and to include radiological hazards as a subset of chemical hazards.

2. Management of Controls:

FDA agrees with food industry comments that not all preventive controls need to be managed with the same level of rigor as CCPs. Indeed, without using the industry characterization of “sliding scale,” FDA nevertheless repeatedly uses the phrase “as appropriate to the preventive control” in each section of the proposed regulations dealing with monitoring, corrective actions, and verification

(including validation) activities. Going further, FDA explicitly proposes not to require validation for food allergen or sanitation controls. ^{3/} FDA refers to monitoring, correction actions, and verification activities as “management components.” FDA also proposes to clarify that parameters and their values are associated with process controls. The revised regulations also would have separate sections for validation, implementation and effectiveness, and reanalysis.

3. Product Testing:

FDA specifically responds to industry requests and provides proposed regulatory language for product testing requirements. These provide the food industry with flexibility on when to conduct product testing. Indeed, FDA has proposed that all verification activities, including product testing, be conducted “as appropriate to the facility, the food and the nature of the preventive control.” In the provision on corrective actions, the agency does suggest that ready-to-eat foods (RTE) would be appropriate candidates for product testing, by requiring, as appropriate, corrective action procedures to address the presence of a pathogen or indicator organism in a RTE food detected as a result of product testing. Note that FDA agrees with industry comments that this section should be called “product testing” rather than “finished product testing,” consistent with the FSMA terminology, and that product testing is a verification activity, not a control activity.

4. Environmental Monitoring:

Like for product testing, FDA proposes specific regulatory language for environmental monitoring requirements in response to industry requests. FDA also proposes the same general framework for environmental monitoring, by stating that such monitoring would be conducted as a verification activity “as appropriate to the facility, the food and the nature of the preventive control.” The supplemental proposal provides for such testing if “contamination of a ready-to-eat food with an environmental pathogen is a significant hazard.” Each facility would be required to have written procedures for environmental monitoring, but it would be up to the facility to determine where, when, and how much sampling to undertake. Notably, FDA makes no reference to Zone 1 testing. FDA also proposes to revise the definition of “environmental pathogen” to specify that it does not include the spores of pathogenic sporeformers.

5. Supplier Verification:

Likely reflecting concerns with ingredient-based recalls, some of the most detailed requirements in the preventive controls regulations would address supplier verification programs. In response to industry requests, FDA proposes specific regulatory language for supplier verification programs. Overall, these requirements align with the foreign supplier verification program (FSVP) proposed regulations. FDA proposes to limit supplier verification to those circumstances where the supplier is responsible for controlling the significant hazard (biological, chemical, or physical) – i.e., no requirements would apply where the manufacturer (or the manufacturer’s downstream customer) is responsible for controlling the hazard.

On the subject of the frequency of onsite audits, which drew considerable industry comment in the original FSVP proposed rule, FDA proposed a hybrid approach whereby, if the supplier was responsible for controlling a hazard that could cause serious adverse health consequences or death to humans or animals (SAHCODHA): (a) there would be a requirement for an initial audit and an annual onsite audit thereafter; but (b) the receiving facility would have the ability to document why

^{3/} FDA also proposed to use the term “allergen cross contact” rather than “cross contact” to reduce the potential for confusion with the term “cross contamination” in the human food GMPs.

other verification activities and/or less frequent onsite audits provide adequate assurances that the hazards are controlled. In this way, FDA agrees with industry comments that supplier oversight should take into account both the risk of the ingredient and the risk (i.e., track record) of the supplier.

FDA also agrees with industry comments that the audit report itself would not be accessible to the agency; instead, the manufacturer would be required to provide the conclusions of the audit and corrective actions taken in response to significant deficiencies. In addition, FDA proposes that instead of an onsite audit, a receiving facility could rely on the results of an inspection of the supplier by FDA or by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or equivalent.

Notably, FDA continued to propose that any onsite audit be conducted by a “qualified auditor,” but makes no mention of the accreditation of third party auditors program. This may be an additional area for comment.

Finally, FDA proposes regulatory language in the FSVP supplemental proposed rule stating that when importers or their customers are in compliance with the supplier program requirements in the preventive controls regulations, the importers would be deemed in compliance with most FSVP requirements (in cases involving customer compliance with preventive controls supplier program requirements, the importer would need to obtain written assurance of compliance annually).

6. Economically Motivated Adulteration:

Although most recent industry comments regarding economically motivated adulteration (EMA) recommended no regulatory requirements to address EMA at this time, in this supplemental notice FDA has formally proposed that EMA be included within preventive controls rules as part of the hazard analysis (“hazards that may be intentionally introduced for purposes of economic gain”). This is the one area where FDA clearly disagrees with industry comments and therefore warrants close scrutiny.

7. Definition of “Farms”:

FDA is proposing to revise the definition of “farm” as well as definitions for three activities (“harvesting,” “holding,” and “packing”) that play a key role in determining whether an establishment is within the “farm” definition and thus exempt from registration and requirements conditional on facility registration (e.g., preventive controls). In general, the supplemental proposal reduces the occasions where a farm would have to register (e.g., when conducting farm-like activities on produce from neighboring farms). Importantly, the revised definitions would not create any new circumstances where a farm that would not have been required to register under the previous proposal would now be required to register.

8. Human Food By-Products Diverted to Animal Feed:

In the supplemental animal food proposal, FDA agrees with industry comments that human food by-products or waste that are to be diverted to animal feed, should not be subject to the full set of regulations designed for animal food manufacturers. Instead, FDA proposes that, because these foods are subject to the human preventive controls regulations up to the point of diversion, at that point they should only be subject to selective good manufacturing practices (GMP) regulations related to the holding and distribution of animal food.

9. Animal Food GMPs:

In response to industry comments, FDA proposes revisions to the GMPs for animal food. Although they use the same structure as human food GMPs, these revisions are designed to make the GMPs for pet food facilities and livestock feed facilities more flexible and tailored to animal food production.

10. Very Small Businesses and Qualified Facilities:

In the human food rule, FDA proposed to define “very small business” as one with annual sales under \$1,000,000. In the animal food rule, FDA proposes to define a very small business as one that has less than \$2.5 million in total annual sales of animal food. Under both sets of regulations, all very small businesses would be “qualified facilities” and subject to modified requirements.

FDA proposes expanded due process procedures that would be employed before any “qualified facility” lost its exemption, as well as a procedure for re-instatement of a withdrawn exemption.

Additional details on many of these issues are contained in the attachment to this memorandum. In addition, FDA will publish redline versions of the proposed regulations for both human and animal food in the respective dockets on regulations.gov.

* * *

We will continue to closely monitor all developments related to FDA’s implementation of FSMA. If you have any questions regarding the supplemental proposed rules, please do not hesitate to contact us.

ATTACHMENT

Summary of Proposed Revisions from the Preventive Controls Supplemental Proposed Rules

1. Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

FDA proposes to eliminate the term “reasonably likely to occur” throughout the regulations and to use the new term “significant hazard” instead. A “significant hazard” would mean a “known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control.”

FDA would expect a facility to first narrow “hazards” to those hazards that are known or reasonably foreseeable. Then the facility would narrow the known or reasonably foreseeable hazards to those “significant hazards” by assessing “the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.”

Importantly, the supplemental proposal provides that the level of oversight for the various preventive controls (referred to as “management components”) is flexible based on the nature of the control. This reflects what industry comments referred to as a “sliding scale” and would essentially codify current industry practices (that CCPs require more extensive oversight than non-CCPs and that the level of oversight for non-CCPs varies as well). It would be up to each facility to specify in its food safety plan the level of oversight needed for the preventive controls being utilized.

In addition, the regulations would explicitly provide:

- Preventive controls include controls other than those at critical control points (CCPs) (e.g., zoning, preventive maintenance);
- That there may not be any controls at CCPs; and,
- Recordkeeping requirements do not require duplication of existing records if those records contain all required information and satisfy the recordkeeping requirements. Additionally, required information does not need to be kept in one set of records.

The agency also recognizes that allergen controls and supplier controls are not “process controls”; not all monitoring activities generate records; not all corrections require records; not all preventive controls require validation (such as segregation of allergens, training, preventive maintenance, and refrigeration); and not all corrective actions require verification.

2. Product Testing

FDA proposes to require product testing as a verification activity, as appropriate to the facility, the food, and the nature of the preventive control. The term “product testing” would encompass ingredient testing, in-process testing, and finished product testing. Product testing procedures, which would be written, would be required to specify the procedures for identifying samples and the procedures for sampling. In addition, facility corrective action procedures would be required to

address the presence of an environmental pathogen or appropriate indicator organism in a RTE product detected through product testing. In addition to the specific proposed regulatory language, FDA is reopening the comment period with respect to the agency's previous request for comment on when and how product testing programs are appropriate.

3. Environmental Monitoring

FDA proposes to require environmental monitoring if contamination of a RTE food with an environmental pathogen is a significant hazard and otherwise as appropriate to the facility, the food, and the nature of the preventive control. The regulations also would establish requirements for performing, as part of the hazard evaluation, an evaluation of environmental pathogens whenever a RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen. Environmental monitoring procedures, which would be written, would need to identify the locations and sites for routine environmental monitoring and the timing and frequency, which would need to be adequate to determine whether preventive controls are effective. Additionally, facility corrective action procedures would need to address the presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring. Like with product testing, in addition to specific proposed regulatory language, FDA is reopening the comment period with respect to the agency's previous request for comment on when and how environmental monitoring programs are appropriate.

4. Supplier Verification

Scope. FDA proposes to require a "supplier program" for raw materials and ingredients for which the receiving facility has identified a significant hazard (biological, chemical or physical) when the hazard is controlled before receipt of the raw material or ingredient. Supplier program requirements would not apply to materials for which there are no significant hazards, the preventive controls at the receiving facility are adequate, or the receiving facility relies on the customer and obtains written assurance the customer is controlling the hazards. "Suppliers" are establishments that manufacture/process food, raise animals, or harvest food that is provided to a receiving facility without further processing by another establishment (except for further manufacturing that is solely the addition of labeling or similar activity of a de minimis nature). "Receiving facilities" manufacture/process raw materials or ingredients that they receive from suppliers.

Thus, a facility that packs or holds food without any manufacturing would not be a supplier and a facility would not be required to establish a supplier program for food it only packs or distributes. However, if a receiving facility receives material from a distribution center and the receiving facility has identified a significant hazard in that material that is controlled by the supplier (the manufacturer or farm), the receiving facility (not the distribution center) would need to establish supplier verification activities related to the manufacturer or farm that provided the material to the distribution center. If a facility receives an ingredient from a supplier, but the hazard is controlled by the supplier's supplier, the receiving facility would conduct supplier verification activities that would include verifying that the supplier has conducted appropriate verification that *its* supplier has controlled the hazard (i.e., the receiving facility would review the supplier's food safety records for its supplier's control of the hazard). FDA is seeking comment on how supplier verification activities should address gaps in the system where: (a) materials pass through more than one facility that would not be required to verify control of hazards (e.g., various distributors which ship to retailers); and (b) raw agricultural commodities such as fresh produce will not be handled by any facilities that would be required to have preventive controls (and, hence, supplier verification responsibilities) before reaching consumers.

Verification Activities. FDA proposes to require verification activities, and documentation of such, to ensure materials are received only from approved suppliers. (When necessary and appropriate, materials could be received on a temporary basis from unapproved suppliers whose materials the receiving facility subjects to adequate verification activities before acceptance for use). The agency also proposes to require verification activities to verify the hazard is significantly minimized or prevented, the material is not adulterated or misbranded under section 403(w) (undeclared allergens), and the material was produced in compliance with applicable FDA food safety regulations. Facilities would have the flexibility to determine the appropriate verification activities based on several factors: (1) the severity of the hazard; (2) where the preventive controls for those hazards are applied; (3) the supplier's food safety practices; (4) the supplier's compliance with FDA food safety regulations; (5) the supplier's food safety performance history; and (6) any other factors, such as storage and transportation.

When there is a reasonable probability that exposure to the hazard will result in SAHCODHA, the regulations would require an initial onsite audit and annually thereafter unless the facility documents its determination that other verification activities and/or less frequent audits provide adequate assurance that the hazards are controlled. Further, facilities could conduct alternative verification activities for materials received from qualified facilities or a farm not subject to requirements under the produce safety rule. Audits would need to be conducted by a qualified individual who has technical expertise obtained by a combination of training and experience. Inspections by FDA or an officially recognized or equivalent food safety authority may substitute for an audit. Companies would need to take action to address supplier non-conformance and document such action.

Documentation. FDA also proposes to require documentation of the activities associated with the supplier program, including requiring a written supplier program and documentation demonstrating that products are received only from approved suppliers (but importantly, a list of approved suppliers would not be required). FDA also proposes to establish minimum requirements for records documenting an audit, records of sampling and testing, records documenting review of the supplier's relevant food safety records, and documentation of alternative verification activities for suppliers that are qualified facilities or farms not subject to the produce rule. Audit related records would need to document the procedure used, the conclusions of the audit, and corrective actions taken in response to significant deficiencies, but would not need to include the underlying audit report. In the preamble to the supplemental proposed rule, FDA explains that even if a supplier program is established and maintained by a facility's corporate headquarters or parent entity, the agency would expect many of the records for such a program to be accessible during facility inspections because they would be in electronic form (electronic records would be considered onsite if they are accessible from an onsite location). This runs counter to industry comments that inspection of supplier verification programs would best be conducted at the headquarters facility where the program is conducted and the records are maintained.

FDA is reopening the comment period with respect to its previous request for comment on when and how supplier programs are appropriate. The agency also is requesting comment on whether it should include requirements to address conflicts of interest for individuals conducting supplier verification activities and the scope of such requirements.

Relationship to FSVP. Also note that in the FSVP supplemental proposed rule, FDA proposes to specify, in the revised regulatory text, that if an importer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer is in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulations (except for the requirement to identify the importer at entry of the food into the United States). Similarly, if an importer's customer is required to establish and

implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer annually obtains written assurance that its customer is in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulations (except for the requirement to identify the importer at entry of the food into the United States and the requirement to maintain records of the written assurances). Further, if the preventive controls that an importer and/or its customer implements under the preventive controls regulations are adequate to significantly minimize or prevent all significant hazards in a food, the importer is not required to determine or conduct foreign supplier verification activities. If the importer's customer controls one or more significant hazards in a food, the importer must annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

5. Economically Motivated Adulteration

FDA proposes to require the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain. In the preamble, FDA explains that the focus would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value. FDA believes that is practicable to determine whether EMA is reasonably foreseeable by focusing on circumstances where there has been a pattern of such adulteration in the past, suggesting there could be the potential for intentional adulteration even though the past occurrences may not be associated with the specific supplier or the specific food product. FDA cites a recent report from the Congressional Research Service as a source of information on past EMA incidents.

6. The "Farm" Definition

FDA is proposing to revise the definition of "farm" as well as definitions for three activities ("harvesting," "holding," and "packing") that play a key role in determining whether an establishment is within the "farm" definition and thus exempt from registration and requirements conditional on facility registration (e.g., preventive controls, mandatory recall, the reportable food registry, and one-up, one-back recordkeeping).

Significantly, a farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities (RACs) grown on another farm not under the same ownership. In addition, a "farm" could manufacture/process RACs by drying/dehydrating to create a distinct commodity (e.g., drying grapes to create raisins), and package and label the dried commodity, as long as there was no additional processing (such as slicing fruit before drying it or applying sulfites). Although the "farm" conducting drying/dehydrating that is akin to harvesting would be exempt from registration and preventive controls requirements, because the drying/dehydrating of RACs to create distinct commodity creates a processed food, the packaging, packing, and holding of such food (e.g., the raisins) would be subject to GMP requirements. However, FDA proposes to specify in the regulations that compliance with the GMPs may be achieved by complying with the applicable requirements for packing and holding produce RACs in the produce safety rule.

Under the revised "farm" definition, it will be clear that an establishment devoted to the growing of crops, the raising of animals, or both, can remain within the "farm" definition if it packages RACs grown or raised on a farm to prepare them for storage and transport, without additional manufacturing/processing (e.g., application of modified atmosphere packaging). Packaging activities would continue to be considered manufacturing/processing; however, packaging a RAC would not transform the RAC into a processed food. A farm that also manufacturers/processes

products such as dried, cut apples would be a farm mixed-type facility, subject to registration and preventive controls requirements.

Other changes would:

- Provide for “field coring” as an example of a harvesting activity to make clear that on farm “field coring” of a RAC is an activity that is within the “farm” definition;
- Provide that activities performed incidental to packing a food would be “packing” activities (e.g., activities performed for the safe or effective packing of that food, such as sorting, culling, and grading) and provide that this definition would apply to all establishments that pack food, not just to farms and farm mixed-type facilities; and,
- Provide that activities performed incidental to holding a food would be “holding” activities (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessary for the distribution of that food, such as affixing labels and breaking down or assembling pallets, controlling pests, blending of the same commodity) and provide that the revised definition applies to all food, not just RACs, and all facilities that hold food, not just farms and mixed-type facilities.

FDA also is proposing to clarify that the human food GMPs do not apply to fishing vessels that are not subject to food facility registration requirements. Likewise, the human food GMPs do not apply to hulling, shelling, and drying nuts (without manufacturing/processing such as roasting). These are activities conducted by establishments engaged solely in the harvesting, storage, or distribution of one or more RACs and, thus, fall within the current RAC exemption in current § 110.19. Fermenting cocoa beans and coffee beans would be classified as “holding” rather than as “harvesting.”

7. Diversion of By-Products to Animal Food

Human food processors already complying with human food safety requirements would not need to implement additional preventive controls or current Good Manufacturing Practice (GMP) regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except for proposed GMPs to prevent physical and chemical contamination when holding and distributing the by-product (e.g., ensuring the by-product is not comingled with garbage). However, further processing a by-product for sale and use as animal food (e.g., drying, pelleting, heat-treatment) would require compliance with the Preventive Controls for Animal Food rule.

FDA notes that the exemption for human food by-products for use in animal food would not apply when contamination or adulteration has occurred that is material to food safety. The agency has two Compliance Policy Guides (Sec. 675.100 and Sec. 675.200) that provide guidance to facilities that want to divert contaminated or adulterated human food for animal use. FDA requests comment on these guides and whether it should include regulations for requests to divert such product to animal food. Further, the exemption would not apply to human food by-products derived from animal products such as meat, offal, or poultry.

The new GMP requirements for holding and distributing human food by-products for use as animal food would include the following:

- Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

- Animal food held for distribution must be held in such a way to prevent contamination from sources such as trash and garbage;
- Labeling identifying the by-product by the common or usual name must be affixed to or accompany animal food; and,
- Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

These limited GMP requirements for holding and distribution would appear in both the human food GMPs in Part 117, as well as the animal food GMPs, Part 507, for ease of reference.

8. Revisions to the Animal Food GMPs

FDA's proposes extensive revisions to the GMPS for animal food that are designed to reflect the difficulty of applying human food GMPs to pet food facilities and livestock feed facilities. The agency believes these revised GMPs are more applicable to the animal food industry and provide flexibility for a wide diversity of types of facilities.

Changes to the proposed GMPs include the following:

- No longer requiring employees to report illnesses to their supervisors;
- Dividing sanitation requirements into two categories—(1) pertaining to buildings, fixtures, and other physical facilities and (2) pertaining to utensils and equipment;
- Changing the section on “sanitary facilities and controls” to address only “water supply and plumbing;”
- Revising the section on “processes and controls” to address “plant operations” and
 - Adding requirements in this section that all animal food operations be conducted under conditions and controls as necessary to minimize the potential for the growth of microorganisms or for the contamination of food;
 - Omitting the requirement that raw materials and ingredients must not contain microorganisms injurious to human or animal health, or the raw materials and ingredients must be treated to eliminate them. This change was made because FDA does not intend that incoming raw materials and ingredients must be tested for pathogens, though the facility may choose to do so.
 - Deleting requirements pertaining to processes and products used for human food but not animal food, such as heat blanching, batters, breading, sauces, and dressings.
- Changing the section on warehousing and distribution” to “holding and distribution” and adding specific requirements such as:
 - Animal food held for distribution must be held under conditions (for example, appropriate temperature, relative humidity, appropriate holding time) that minimize

the potential for growth of undesirable microorganisms and must be held in a way that prevents contamination from sources such as trash and garbage;

- Labeling identifying the product by the common or usual name must be affixed to or accompany the animal food;
- Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food; and,
- Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

9. Definition of a Very Small Business

FDA is proposing to define a very small business as a business that has less than \$1 million in total annual sales of human food, adjusted for inflation. In the animal food rule, FDA proposes to define a very small business as one that has less than \$2.5 million in total annual sales of animal food. Which facilities are considered part of a very small business affects the compliance date for those facilities, the exemption for qualified facilities, and the exemptions for on-farm low-risk packing and holding activity/food combinations and on-farm low-risk manufacturing/processing activity combinations.

Specifically, the proposed definitions of \$ 1 million or \$2.5 million in annual sales would simplify a facility's determination of whether it is a qualified facility and essentially make "very small business" and "qualified facility" synonymous. Under the statute, a facility is a qualified facility if it is either a "very small business" or it had average food sales of less than \$500,000 during the preceding 3-year period, and it primarily sells food directly to "qualified end-users" (i.e., consumers of the food or restaurants or retail food establishments located within the same state or 275 miles of the facility and purchasing the food for sale directly to consumers). Because the dollar threshold for qualifying as a "very small business" encompasses the second set of criteria, the facility would only need to calculate its total sales of human (and/or animal) food rather than determine how much food was sold to qualified end-users and whether food was only distributed within a specified radius.

10. Withdrawal of an Exemption for a Qualified Facility

Under FSMA, "qualified facilities" are exempt from the preventive controls requirements and are subject to modified requirements. This exemption, however, can be withdrawn (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or (2) If FDA determines it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the facility that are material to food safety. In the supplemental proposed rule, FDA proposes to revise the proposed regulations governing the withdrawal of qualified facility's exemption.

FDA proposes to include specific regulatory actions the agency must take before issuing an order to withdraw an exemption, including notifying the facility in writing of the circumstances that may lead FDA to withdraw the exemption, providing an opportunity for the facility to respond in writing within 10 days, and considering the corrective actions taken by the facility. The agency, before issuing an order, could consider alternative actions such as a warning letter, recall, administrative detention, suspension of registration, import alert, or seizure. The regulations would clarify that an order to

withdraw an exemption must be approved by an FDA District Director before it can be issued and would provide a process for reinstating an exemption that had been withdrawn. The order would explain that the facility must either comply with the preventive controls requirements within 120 days or appeal the order within 10 days. FDA also is proposing to provide for re-instatement of an exemption either on its own initiative or in response to a written request from the facility that includes information demonstrating that the facility has adequately resolved the problematic conditions or conduct.

MEMORANDUM

From: Joseph A. Levitt
Elizabeth Barr Fawell
Veronica Colas

Date: September 26, 2014

Re: **FDA Re-Issues Key Sections of Produce Safety Proposed Rule Under FSMA**

As part of its continued implementation of the FDA Food Safety Modernization Act (FSMA), on September 19th, FDA issued a supplemental proposed rule that offers revised language on several key provisions in the produce safety proposed rule. In response to the extensive comments received, FDA states that it has made “significant changes” in its thinking on certain provisions of the proposed rule, which was initially published in January 2013. The agency is reopening the comment period only with respect to these specific issues.

The provisions included within the re-proposal fall into three general categories: (1) the scope of the proposed rule, including which farms and activities are covered; (2) new provisions regarding the withdrawal and reinstatement of a qualified exemption from the produce safety standards; and (3) revisions to specific produce safety standards for agricultural water, biological soil amendments, and domesticated and wild animals. Below we describe each of the proposed changes, with emphasis given to the first two categories. Comments on the supplemental proposed rule are due December 15, 2014.

Changes to the Scope of the Proposed Rule

Which Farms Are Covered?

FDA’s first proposed change relates to which farms are considered “covered farms” subject to the produce safety rule in part 112. Originally, FDA proposed to apply the produce safety regulation to only farms and farm mixed-type facilities with an average annual monetary value of all food sold during the previous 3-year period of more than \$25,000 (on a rolling basis). Farms with average sales less than \$25,000 during the previous 3-year period would be completely excluded from the rule’s coverage. Under the supplemental proposal, FDA would apply the \$25,000 limit to sales of produce rather than sales of all food. FDA states that it believes this modification will accommodate the concerns expressed by some commenters that making coverage turn on sales of all food would make it difficult for farms to diversify their operations and would have an adverse impact on diversified farms. The agency declined, however, to apply the \$25,000 limit to the average annual monetary value of covered produce, finding that the likely frequent changes to a farm’s covered or non-covered status presented challenges in terms of compliance and enforcement, as well as in determining the public health impact of this approach. FDA seeks comment on this proposed amendment.

FDA is also proposing to make corresponding revisions to the definitions of “very small business” and “small business” so that the monetary thresholds for all categories of business apply to the average annual sales of “produce” rather than of “all food.” In particular, a “very small business” would be defined as a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$250,000. A “small business” would be defined as a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$500,000. FDA did not make a corresponding change to the eligibility criteria for a “qualified exemption” because the statutory language specified that “all food” must be considered in calculating sales.

Definition of Farm

Second, FDA proposes an expanded definition of the term “farm” in response to comments about overlap between the produce safety and preventive controls rules. Under the initial proposal, packing or holding of produce would be subject to either the preventive controls rule or the produce safety regulation, depending on whether or not the produce was grown or harvested on a farm under the same ownership. Commenters objected that this distinction lacks a public health basis, would be burdensome and arbitrary, and would infringe upon the common industry practice for neighboring farms to pack or hold produce grown or harvested by the other. FDA agreed that packing or holding of produce presents similar reasonably foreseeable hazards regardless of whether the produce is grown and harvested on farms under the same or different ownership, and that such hazards associated with packing or holding activities would best be addressed under the produce safety standards (rather than under the preventive controls rule).

Therefore, FDA is proposing to revise the definition of “farm,” such that packing or holding others’ raw agricultural commodity (RAC) produce on a covered farm would now be subject to the produce safety standards. The agency is also proposing corresponding revisions to the definitions of “covered activity,” “harvesting,” “holding,” and “packing” so that each of these definitions would encompass the relevant activities regardless of the ownership of the farm where the RACs were grown.

The agency is proposing additional amendments to the definitions of “farm,” “holding,” and “packing,” consistent with proposed changes in the amended proposed rule on preventive controls for human food. ^{1/} Specifically, FDA would make the following changes:

1. Revise the definition of “farm” to include: (a) establishments that manufacture/process food by drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; as well as (b) manufacturing/processing food by packaging and labeling RACs, when these activities do not involve additional manufacturing/processing (e.g., a covered farm placing strawberries in a plastic “clamshell” package);
2. Refer to “establishments” rather than to “facilities” in the definition of farm;
3. Amend the definition of “holding” to also include activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same RAC and breaking down pallets)); and

^{1/} See HL Memorandum, *FDA Issues Supplemental Preventive Controls Rules Under FSMA*, September 26, 2014.

4. Revise the definition of “packing” to also include activities performed incidental to packing a food (e.g., activities performed for the sale or effective packing of that food (such as sorting, culling and grading)).

Beyond these proposed changes, FDA requests comments on three key issues related to the definition of “farm”:

1. Should the phrase “in one general physical location” be included in the farm definition in the final rule? If so, how should FDA interpret this phrase?
2. In instances where a farm supplies its produce to another farm to pack, hold, or store the produce, should the farms involved be subject to a requirement to establish and maintain a record of the produce shipment for tracking purposes in the event of an illness outbreak?
3. Should on-farm packinghouses under cooperative ownership by multiple growers be considered under the same ownership as any or all of the growers’ farms, for the purposes of this regulation?

New Provisions Regarding the Withdrawal and Reinstatement of a Qualified Exemption

Withdrawal of a Qualified Exemption

The agency is proposing new provisions related to the “qualified exemption,” which provides modified requirements for farms with average food sales during the previous 3-year period of \$500,000 or less that sell primarily to consumers, retail food establishments, or restaurants located within the same state or a 275 mile radius of the farm. ^{2/} FDA originally proposed that it could withdraw a farm’s qualified exemption in the event of a foodborne illness outbreak directly linked to the farm or if FDA determines it is necessary to protect public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the produce.

In the supplemental proposed rule, FDA proposes to require that before FDA issues an order to withdraw a qualified exemption, FDA would need to provide to the farm a notification of the problems identified by the agency and an opportunity to respond to the notification within 10 calendar days. The agency would be required to consider the farm’s response prior to proceeding with issuing an order withdrawing the exemption. FDA also proposes changes to clarify that a withdrawal order must be approved by an FDA District Director in whose district the farm is located, or an FDA official senior to such Director (or, for a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)).

The supplemental proposal would also state that prior to withdrawing an exemption, the agency “may” consider “other actions, as appropriate,” to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, mandatory recall, administrative detention, refusal of food offered for import, seizure, and injunction. If these other actions address the circumstances at issue, then FDA would likely determine that withdrawal of the exemption is not needed. In the preamble, FDA explains two scenarios that illustrate the agency’s likely approach when considering such other actions. ^{3/}

^{2/} The qualified facility exception was added to the statute via the “Tester amendment.” FSMA § 103; FFDCA § 418.

^{3/} See pages 116-118 of the pre-publication version of the proposed rule. FDA gives the examples of Farm A, which produces heirloom tomatoes that are epidemiologically linked to an outbreak of salmonellosis; and Farm B, which produces green onions that test positive for *Shigella*.

Reinstatement of a Qualified Exemption

The supplemental proposal includes a new provision establishing the process for reinstatement of a qualified exemption that is withdrawn. This provision would provide that if the local FDA District Director (or Director of the Office of Compliance in CFSAN for a foreign farm) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at the farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate an outbreak, he or she is to reinstate the exemption, either on his or her own initiative or at the request of the farm. The amended proposal would also establish a process for a farm to request reinstatement of the exemption by submitting written data and information to demonstrate that the problems have been resolved.

If FDA withdraws a farm's exemption under section 112.201(a)(1) (i.e., in the course of an active outbreak investigation that is directly linked to that farm), and FDA later determines that the outbreak is not directly linked to that farm, FDA will reinstate the exemption on its own initiative. In contrast, if the withdrawal is issued under both sections 112.201(a)(1) and 112.201(a)((2) (i.e., if FDA determines that the withdrawal is necessary based on conduct or conditions associated with the farm that are material to food safety), and FDA later determines that the outbreak is not directly linked to that farm, the farm may submit a request that FDA reinstate the qualified exemption. In the latter case, FDA would not be required to reinstate the exemption on its own initiative.

Changes to the Standards for Three of the Six Specific Hazards

Lastly, FDA proposes significant changes related to three of the six specific hazards in the proposed rule. Below we provide a topline summary of the proposed changes for each hazard, which are generally aimed at providing increased flexibility for covered farms.

- Agricultural Water: FDA would (1) update and incorporate additional flexibility for meeting the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method; (2) amend the provisions regarding frequency of testing agricultural water to provide greater flexibility to farms; and (3) provide that a farm may meet the requirements related to agricultural water testing using the farm's own test results or data collected by a third party or parties in certain circumstances.
- Biological Soil Amendments: The agency proposes to amend the standards for using raw manure and compost. In particular, FDA would (1) remove the proposed 9-month minimum application interval for use of raw manure, deferring the decision on an appropriate time interval until FDA conducts further risk assessment and research work; and (2) remove the proposed 45-day minimum application interval for use of a biological soil amendment of

In the examples, Farm A conditions and practices are generally consistent with good agricultural practices and management appears to be committed to food safety; while an inspection of Farm B indicates that the establishment is lacking certain prerequisite programs and is not in compliance with the proposed provisions in the produce safety rule. The agency explains that for both farms, it will provide education, request that the farm correct certain procedures and practices, and re-evaluate the company's corrective actions during a future inspection. If, at that time, FDA finds that Farm A has not voluntarily taken appropriate steps to correct the conditions or conduct that led to the outbreak; or during an inspection of Farm B finds continued conditions or conduct that could result in unsafe food, the agency may pursue withdrawal of each farm's respective exemption. For Farm B, FDA might also seek an injunction.

animal origin that is treated by a composting process and applied in a manner that minimizes the potential for contact with covered produce during and after application.

- Domesticated and Wild Animals: FDA would add a provision to explicitly state that the regulation does not authorize or require covered farms to take actions that would constitute the “taking” of threatened or endangered species in violation of the Endangered Species Act, or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

FDA also states its intent in the preamble to prepare and publish an Environmental Impact Assessment (EIS) in the final rule. The EIS will evaluate the potential environmental effects of the rule, including those resulting from the standards for domesticated and wild animals.

Additionally, the agency has updated its Preliminary Regulatory Impact Analysis (PRIA) and estimates that, compared to the original proposed rule, the supplemental proposed rule provides a cost savings of \$73 million with a decrease in overall net benefits of \$7 million.

* * *

We will continue to closely monitor all developments related to FDA’s implementation of FSMA. If you have any questions regarding the proposed rule, please do not hesitate to contact us.



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Update on Stockholder Books and Records Inspection Demands and Derivative Litigation

David F. Graham

October 16, 2014

Demands for Inspection of Company Books and Records

- Delaware Corporation Law Section 220 provides the right to inspect corporate records.
- Philosophy underlying inspection rights: “As a matter of self protection, the stockholder was entitled to know how his agents were conducting the affairs of the corporation...” *Shaw v. Agri-Mark, Inc.*, 663 A.2d 464, 467 (Del. 1995).
- Demand must be in writing, state with specificity the purpose of the inspection, and identify with precision the documents sought.

What Are the Procedures and Time Frames Related to Section 220?

- Corporation must respond to a Section 220 demand within five business days.
- In the event that a dispute arises regarding the corporation's response, the Delaware Court of Chancery is required to hold expedited proceedings and "may summarily order" the corporation to provide inspection.
- Delaware courts frown upon motions to dismiss Section 220 enforcement requests and prefer to hold summary evidentiary hearings.
- Court may condition inspection upon entry of appropriate confidentiality order prohibiting dissemination of materials received.
 - However, requests to permit dissemination of documents in connection with subsequent pleadings have not infrequently been granted.

Who Has the Right to Inspect Books and Records?

- Any stockholder of the corporation. No minimum stock ownership requirement.
- A designated representative of the stockholder.
 - Typically the stockholder's attorney and often a plaintiffs' class action law firm.
- Directors also have inspection rights under Section 220.
 - Important with respect to dissident directors.

What Can Be Inspected?

- Company's stock ledger or list of stockholders
 - If corporation opposes inspection, it bears the burden of proof in establishing that the stockholder's purpose is improper.
- Section 220 also broadly permits inspection of "other books and records."
 - "[B]ooks and records" is an undefined phrase and has been given broad scope by Delaware courts, extending to virtually all corporate documents.
 - Courts regularly require the production of board and subcommittee presentations, minutes, and communications as well as special committee documents. Other common areas include documents concerning categories of internal controls, investigations by government agencies, and statements made to the company's auditor.
 - Subsidiary books and records have also been included within the scope of inspection for publicly-held corporations.
 - In contrast to a request for stock ledger or list of stockholders, the burden of proof is on the stockholder to establish that inspection of "other books and records" is sought for a proper purpose.

Limitations on the Scope of Inspection

- A Section 220 demand must be made with “rifled precision” and must only seek books and records “necessary” and “essential” to the stockholder’s proper purpose. *Saito v. McKesson HBOC, Inc.*, 806 A.2d 113, 117 & n.10 (Del. 2002)
 - Section 220 inspections have been distinguished from the broader scope of litigation discovery. *See, e.g., Cook v. Hewlett-Packard Co.*, 2014 WL 311111, at *3 (Del. Ch. Jan. 30, 2014).

What Is a Proper Purpose for Inspection?

- “[A] purpose reasonably related to [the stockholder]’s interest as a stockholder.” 8. Del.C. §220(b).
- A very broad set of purposes have been found to be proper. A nonexhaustive list includes:
 - determining the suitability of directors to serve on a board (*Pershing Square, L.P. v. Ceridian Corp.*, 923 A.2d 810, 817-18 (Del. Ch. 2007));
 - communicating with other stockholders;
 - performing a valuation of the stockholder’s holdings;
 - waging a proxy campaign or formulating a proposal for consideration at a company’s annual meeting (potential tool for activist shareholders).
- One other common stated purpose is to investigate potential wrongdoing.
 - Often undertaken with the aim of making a stockholder demand or preparing a derivative lawsuit.

Required Showing of Wrongdoing or Mismanagement

- A stockholder who seeks to investigate potential wrongdoing or mismanagement must establish, by a preponderance of the evidence, that a credible basis exists from which the court can infer **possible** wrongdoing.
- The credible basis standard “sets the lowest possible burden of proof,” and may be satisfied “through documents, logic, testimony, or otherwise.” *Sec. First Corp. v. U.S. Die Casting & Dev. Co.*, 687 A.2d 563, 568 (Del. 1997)
 - Delaware courts frequently justify the high pleading standard in stockholder derivative actions by pointing to stockholders’ ability to use Section 220 as a tool to meet that pleading standard.

Loosening of Credible Basis Standard

LAMPERS v. The Hershey Company (Del. Ch. Mar. 18, 2014)

- *LAMPERS v. The Hershey Company*, No. 7996-ML (Del. Ch. Mar. 18, 2014) (transcript ruling)
 - LAMPERS sought inspection of Hershey’s books and records to investigate whether the company purchased cocoa produced by child labor in West Africa.
 - LAMPERS’ evidence included that 70% of world’s chocolate came from two countries with documented use of child labor in the cocoa industry; Hershey controlled 42% of the world’s chocolate market; Hershey acknowledged that some of its cocoa products originated in those two countries, and would not disclose its suppliers.
 - Delaware special master recommended dismissal, noting that no source cited in the complaint stated that Hershey had violated the law or was under investigation for possible legal violations, or identified illegal conduct within Hershey.
 - Vice Chancellor Laster rejected recommendation, emphasizing that the showing required for credible basis “may ultimately fall well short of demonstrating that anything wrong occurred.”

Loosening of Credible Basis Standard

Oklahoma Firefighters Pension & Ret. Sys. v. Citigroup Inc.
(Del. Ch. Sept. 30, 2014)

- The same special master who recommended dismissal in *Hershey* recently stated that requiring a stockholder to “have specific and concrete evidence of possible wrongdoing or mismanagement” in order to obtain materials under Section 220 would:
 - “ignore the very low burden of proof required by the credible basis standard” and
 - “threaten to render meaningless the Delaware courts’ repeated urging that stockholder plaintiffs seek books and records before filing class or derivative complaints so they may prepare factually accurate and legally sufficient proceedings.”

Oklahoma Firefighters Pension & Ret. Sys. v. Citigroup Inc., No. 9587-ML, Report of Master LeGrow at 15-16 (Del. Ch. Sept. 30, 2014) (Defs.’ Notice of Exception Pending).

Expanding Scope of 220 Inspections, Including Privileged Documents

Wal-Mart Stores, Inc. v. Indiana Elec. Workers Pension Trust Fund IBEW,
95 A.3d 1264 (Del. 2014)

- *Wal-Mart Stores, Inc. v. Indiana Elec. Workers Pension Trust Fund IBEW*, 95 A.3d 1264 (Del. 2014)
 - Stockholder made a Section 220 demand following *NY Times* article relating to bribes paid to Mexican officials by Wal-Mart’s Mexican subsidiary (“WalMex”)
 - Wal-Mart agreed to produce board materials—including minutes, agendas, and presentations—relating to WalMex allegations, as well as existing policies relating to FCPA compliance. Initial production included over 3,000 documents and was supplemented by two later additional products. Wal-Mart also provided a privilege log.
 - IBEW filed a Section 220 action in Delaware Court of Chancery contending that Wal-Mart had made unwarranted redactions and had failed to produce certain responsive documents, including materials claimed to be privileged.

Expanding Scope of 220 Inspections, Including Privileged Documents

*Wal-Mart Stores, Inc. v. Indiana Elec. Workers Pension Trust Fund
IBEW*, 95 A.3d 1264 (Del. 2014) (cont'd)

- Court of Chancery ordered Wal-Mart to produce:
 - officer (and lower)-level documents regardless of whether they were ever provided to Wal-Mart's Board;
 - documents spanning a seven-year period;
 - documents from disaster recovery tapes; and
 - any additional responsive documents "known to exist" by Wal-Mart's Office of General Counsel, including documents **otherwise** protected by the attorney-client privilege and attorney work-product doctrine.

Expanding Scope of 220 Inspections, Including Privileged Documents

Wal-Mart Stores, Inc. v. Indiana Elec. Workers Pension Trust Fund IBEW, 95 A.3d 1264 (Del. 2014) (cont'd)

- Delaware Supreme Court affirmed the Court of Chancery's order.
 - In affirming, the Delaware Supreme Court held that test set forth in *Garner v. Wolfinbarger*, 430 F.2d 1093 (5th Cir. 1970), for shareholder access to privileged documents in litigation is also applicable to Section 220 inspections.
 - *Garner* test generally holds that, subject to a multifactor balancing test, privileged materials may be obtained by a shareholder in litigation involving his company's actions if a showing of "good cause" is made, including the absence of viable discovery alternatives.
 - In *Wal-Mart Stores, Inc.*, the Supreme Court held that the that stockholder had made the required showing of "good cause." Stockholder had demonstrated a colorable claim against Wal-Mart "based on 'Wal-Mart's own public statements ... [which] suggest that there were some real concerns about what was going on in Mexico and whether it was legal.'" 95 A.3d at 1278 (quoting Court of Chancery transcript decision).
 - Information was not available from other, non-privileged sources because stockholder's claim of wrongdoing related in part to the conduct of Wal-Mart's internal legal counsel in connection with an internal investigation related to WalMex.

Stockholder Derivative Actions

- Expanded scope of corporate books and records inspections important because stockholders often rely upon these materials in crafting derivative action complaints.
- Stockholder derivative actions are lawsuits brought by stockholders seeking to assert a claim on the corporation's behalf against the corporation's management and/or board of directors.
 - Typically brought on the heels of a significant corporate trauma or event
 - Commonly seek to assert claims such as breaches of fiduciary duty, corporate waste, or unjust enrichment
- Stockholder derivative actions "raise important policy considerations because they permit stockholders to take action in place of the corporation's board of directors." *Ala. By-Products v. Cede & Co.*, 657 A.2d 254, 265 (Del. 1995).

Limitations on Ability of Stockholders to Maintain Derivative Actions

- Restrictions on maintenance of derivative actions have been adopted out of recognition that (1) derivative actions inherently impinge upon board authority to manage corporation; and (2) threat of personal liability may discourage board service or director approval of good faith but potentially risky business decisions.
 - **Business judgment rule:** “The key principle upon which this area of ... jurisprudence is based is that the **directors are entitled to a presumption that they were faithful to their fiduciary duties.**” *Beam ex. rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 845 A.2d 1040, 1048 (Del. 2004).
 - Stockholders must plead “**with particularity**” facts giving rise to an inference that demand on the board for the action sought was excused, because a majority of the directors were not independent or disinterested.
 - “Particularity” requirement has been incorporated in Federal Rule of Civil Procedure 23.1 and several state statutes, including Del. Ch. R. 23.1 and 805 ILCS 5/7.80(b).
 - Naming directors as defendants in a derivative action does not suffice to create “interestedness.” The complaint must plead facts showing a “**substantial likelihood**” of director liability. *E.g., Rales v. Blasband*, 634 A.2d 927, 936 (Del. 1993). The “substantial likelihood” standard does not, however, require a plaintiff to demonstrate a reasonable probability of success on the merits. *Id.* at 934.

Limitations on Ability of Stockholders to Maintain Derivative Actions (cont'd)

- Section 102(b)(7) of the Delaware General Corporation Law authorizes corporations to eliminate personal monetary liability of directors for breach of the fiduciary duty of care.
 - **Result: if a Section 102(b)(7) provision has been adopted, the stockholder must plead with particularity that a majority of directors is liable for non-exculpated conduct, i.e., "conduct that is not in good faith or a breach of the duty of loyalty," in order for pre-suit demand to be excused.** *Stone v. Ritter*, 911 A.2d 362, 367 (Del. 2006).
 - Standard may be met "where the fiduciary intentionally acts with a purpose other than that of advancing the best interests of the corporation, where the fiduciary acts with the intent to violate applicable positive law, or where the fiduciary intentionally fails to act in the face of a known duty to act, demonstrating a conscious disregard for his duties." *Id.* at 369.

Recent Cases Suggest an Increasingly Lenient Interpretation of Pleading Requirements – and an Increasingly Broad View of Director Obligations

Westmoreland Cnty. Emp. Ret. Sys. v. Parkinson (“Baxter”), 727 F.3d 719 (7th Cir. 2013)

- Action arose from allegations that Baxter board breached its fiduciary duties by failing to remediate issues with a medical device, which the FDA ultimately banned from the market.
- District Court held that demand was required, noting that a bad outcome does not necessarily indicate bad faith by the board:
 - “The allegations of the Complaint reveal that Baxter tried to correct the problems with the Colleague Pump but failed to do so to the FDA's satisfaction. That Baxter failed to solve the problems, however, does not permit an inference that board ignored the problem or that its efforts were not in good faith. ... For similar reasons, Westmoreland has not rebutted the presumption that the business judgment rule protects the directors' actions. ... Again, that Baxter's remediation efforts were ‘deeply flawed’ says nothing about whether they were in good faith.” 2012 WL 4180566, at *9, 10.

Recent Cases Suggest an Increasingly Lenient Interpretation of Pleading Requirements – and an Increasingly Broad View of Director Obligations

Westmoreland Cnty. Emp. Ret. Sys. v. Parkinson (“Baxter”), 727 F.3d 719 (7th Cir. 2013) (cont’d)

- Seventh Circuit reversed:
 - “While acknowledging that Baxter officials expended considerable company resources in an effort to fix the Pumps in 2006, 2007, and part of 2008, Westmoreland argues that company officials improperly ‘threw in the towel’ by November 2008. ... [T]he district court’s focus on other hypothetical explanations for the defendants’ conduct improperly ignores the rule that ‘any inferences reasonably drawn from the factual allegations of the complaint must be viewed in the light most favorable to the plaintiffs.’” 727 F.3d at 726, 729 (quoting *In re Abbott Labs. Deriv. S’holders Litig.*, 325 F.3d 795, 803 (7th Cir. 2003)).
- Seventh Circuit attached particular importance to reduction in Company remedial expenditures that occurred in late 2008 and 2009, after several hundred million dollars had already been spent by the Company on remedial efforts in preceding years. While the Court acknowledged potentially innocent reasons for the budgetary reduction, it held that it was required to draw reasonable inferences in the plaintiff’s favor. *See id.*

Recent Cases Suggest an Increasingly Lenient Interpretation of Pleading Requirements – and an Increasingly Broad View of Director Obligations

In re Abbott-Depakote S'holder Deriv. Litig. (N.D. Ill. June 5, 2013)

- Action arose from allegations that Abbott engaged in off-label marketing of Depakote between 1998 and 2009. Abbott ultimately agreed to plead guilty to misdemeanor criminal charge, pay civil and criminal fines, and enter into a Corporate Integrity Agreement with the Office of the Inspector General of the Department of Health and Human Services.
- Court denied motion to dismiss, emphasizing “magnitude and duration” of alleged conduct:
 - “Plaintiffs sufficiently alleged Board knowledge because: (1) there was a scheme of substantial magnitude and duration that allegedly occurred when a majority of the Board had been appointed as directors; (2) the Department of Justice sent a letter to Abbott informing it to preserve all documents relating to the marketing of Depakote; and (3) the DOJ issued subpoenas regarding the marketing of Depakote.” 2013 WL 4953686, at *4 (N.D. Ill. Sept. 12, 2013) (denying motion for reconsideration of denial of motion to dismiss).

Recent Cases Suggest an Increasingly Lenient Interpretation of Pleading Requirements – and an Increasingly Broad View of Director Obligations

Rosenbloom v. Pyott (“Allergan”), 765 F.3d 1137 (9th Cir. 2014)

- Action arose from allegations that Allergan had illegally marketed and labeled Botox for off-label sales. In 2010, Allergan settled related *qui tam* actions and pled guilty in criminal case, ultimately paying \$600 million in civil settlements and criminal fine.
- Events gave rise to nearly-identical stockholder derivative actions in California federal court and in Delaware state court. Both actions incorporated references to books and records received from Allergan pursuant to Section 220 requests.
 - U.S. District Court for Central District of California dismissed the action for failure adequately to plead demand futility.
 - A few months later, Vice Chancellor Laster of the Delaware Chancery Court held that demand was excused, and allowed action to proceed.

Recent Cases Suggest an Increasingly Lenient Interpretation of Pleading Requirements – and an Increasingly Broad View of Director Obligations

Rosenbloom v. Pyott (“Allergan”), 765 F.3d 1137 (9th Cir. 2014) (cont’d)

- District Court held that the plaintiffs’ allegations, which related to (1) board approval of strategic plans and other decisions allegedly supporting off-label marketing; and (2) board’s alleged failure to take sufficient action after receiving FDA letters, were insufficient to establish demand futility.
 - “There is [] no evidence of a *decision* by board members to promote the use of off-label marketing, nor are there any facts suggesting that the Directors would be incapable of making an impartial decision concerning litigation. ... The FDA letters referenced in Plaintiffs’ [complaint] are similarly unavailing. ... [T]he Directors’ response to [the additional FDA] letter [cited in the amended complaint] actually proves the opposite of Plaintiffs’ point; the Directors were not aware of the problematic [marketing] slides ... and took appropriate remedial action after learning of [them].” 2012 U.S. Dist. LEXIS 5590, at *8, 10-11 (C.D. Cal. Jan. 17, 2012) (emphasis in original).
- Delaware Chancery Court disagreed, emphasizing that the inferences sought by plaintiff were “not unreasonable”:
 - “It is not unreasonable to infer that the Allergan Board, led by a hard-charging CEO who earned the nickname ‘Mr. Botox,’ could have believed that Allergan knew better than the FDA which Botox applications were safe, particularly off-label uses already approved (or at least permitted) in other countries. It is not unreasonable to infer that the Board and CEO saw the distinction between off-label selling and off-label marketing as a source of legal risk to be managed, rather than a boundary to be avoided.” *La. Mun. Police Emps.’ Ret. Sys. v. Pyott*, 46 A.3d 313, 355 (Del. Ch. 2012).
 - Delaware Supreme Court reversed decision on the ground that federal court dismissal decision was entitled to full faith and credit by Delaware Chancery Court, thus precluding the Delaware plaintiff from re-litigating the issue of demand futility. *See Pyott v. La. Mun. Police Emps.’ Ret. Sys.*, 74 A.3d 612, 617 (Del. 2013).

Recent Cases Suggest an Increasingly Lenient Interpretation of Pleading Requirements – and an Increasingly Broad View of Director Obligations

Rosenbloom v. Pyott (“Allergan”), 765 F.3d 1137 (9th Cir. 2014) (cont’d)

- Ninth Circuit reversed the District Court on appeal, finding a “reasonable inference of conscious inaction” by the Allergan Board, i.e., that the Board likely was aware of and tolerated impermissible marketing of off-label uses. While acknowledging that off-label sales were not themselves impermissible absent improper marketing, the Court attached importance to the following factors:
 - “First, Plaintiffs allege with particularity that the Board continued to closely and regularly monitor off-label Botox sales. ... Second, even as it carefully monitored Allergan's Botox programs and determined that growth of off-label Botox sales was critical to achieving desired profit margins, the Board received data directly linking Allergan’s sales programs to fluctuations in off-label sales. ... Third, the Board received repeated FDA warnings about illegal promotion of Botox. To be sure, many of these warnings concerned only misbranding and other violations of the law, not the specific off-label promotions at issue here. ... Fourth, the illegal conduct in this case involved one of the most important drugs at Allergan. ... Finally, the illegal conduct was unquestionably of significant magnitude and duration.” 765 F.3d at 1152-54.
- Ninth Circuit further held that “the district court committed a number of errors”:
 - “First, [the district court] considered the factual allegations in isolation from each other rather than in combination, even though in cases like this one an inference of Board involvement or knowledge may depend on a combination of factual allegations. **Second, it repeatedly drew inferences in the Board’s favor, crediting Allergan’s reasonable interpretations of the factual allegations over Plaintiffs’ reasonable interpretations of those same.** Finally, the district court essentially insisted on a smoking gun of Board knowledge, even though precedent holds that plaintiffs can show demand futility by alleging particular facts that support an *inference* of conscious inaction.” *Id.* at 1155-56 (internal citations omitted).

Takeaways

- Greater ease of stockholder access to corporate books and records, coupled with evolving interpretation of pleading standards in stockholder derivative actions, leading to increased risk of director liability.
 - Note that plaintiffs in each of the *Allergan*, *Baxter*, and *Abbott-Depakote* cases had access to books and records, which aided them in alleging that demand was excused.
- There is an increased judicial tendency to give stockholders the benefit of the doubt in blaming directors for operational issues that persist, particularly if compliance matters are involved.
- Corporations need to re-consider their approach to document preparation, including preparation of board materials, in light of these trends.
- Highly regulated industries at particular risk of follow-on to any government action or investigation.
 - Important to consider potential stockholder issues from the outset of any such proceeding.