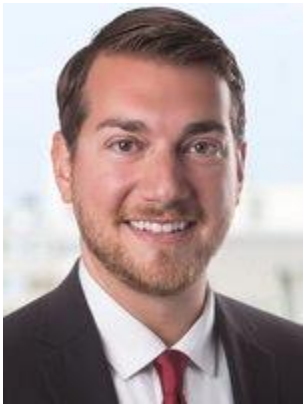
COVID-19 Reveals Tensions In Food Packaging Supply Chain

By **Daniel Rubenstein**



Daniel Rubenstein

The novel coronavirus has impacted nearly every industry throughout the world, fundamentally changing the way that we do business. One of the earliest effects felt in the U.S. occurred when rapid and unexpected changes in consumer behavior led to the temporary lack of availability of certain foods and consumer products, including the packaging that holds these items.

We would later learn that, in many instances, these perceived shortages were not, in fact, shortages at all. Instead, the lack of availability of product was simply the result of an unexpected and rapid increase in the frequency and quantity of purchases that stretched the national and global supply chain to — and in many cases, beyond — its limit.

But it didn't have to be that way. These so-called shortages were a direct result of economic decisions made over many decades, in an attempt to minimize costs — including fixed and variable operating expenses associated with storing raw materials, maintaining warehouse space and accounting for unsold inventory.

COVID-19 has shone a spotlight on the way companies that manufacture food and food packaging maintain their own inventory control systems, and the methods that they use to procure raw materials to produce intermediate products (such as films, resins and additives) or finished packaging. In many instances, the effects of these practices have raised difficult questions about the balance between lean and efficient manufacturing, and a regulated company's responsibility to ensure that it meets the minimum requirements set forth by a regulator.

In the specific case of food and food packaging, both of which are regulated in the U.S. by the U.S. Food and Drug Administration, the pandemic has laid bare the tensions between good supply chain engineering and good manufacturing practice.

Economics Versus Regulatory Compliance: A Necessary Balancing Act

Since the beginning, the overarching goal of lean manufacturing has been to minimize waste — including physical scrap, increased production times, higher material costs, and lower productivity and throughput. Waste is unavoidably inherent to every manufacturing process, and remains prevalent even in light of recent events.

Nevertheless, the extent to which a company embraces lean manufacturing to reduce waste reflects a tradeoff between efficiency and elasticity in the supply chain. Improvements in efficiency and the standardization of a manufacturing process often result in the reduction of available options when something goes wrong.

While concepts such as lean manufacturing and good manufacturing practice are applied in

different ways across the supply chain, their principles are universal. At each decision point in a manufacturing process, a company must determine how many alternatives to make readily accessible and available — recognizing that every additional option necessarily results in a corresponding incremental increase in cost to the process or the product.

In the specific case of products regulated by the FDA, a company faces additional responsibilities to ensure that its manufacturing methods comply with a minimum standard of care, universally identified throughout the various subsets of regulated products through a good manufacturing practice regulatory requirement. The processes and procedures necessary to achieve good manufacturing practice vary, depending on the type of product regulated by the agency.

It is ultimately the responsibility of the manufacturer, distributor or any other company that touches the product to ensure that relevant regulatory requirements are appropriately balanced with the inherent need to maximize efficiency.

Food Packaging: The Substitution Conundrum

Within the scope of food packaging, one of the most critical decisions that a company faces is determining the composition and technical properties of the finished product, and the raw materials necessary to manufacture it. From a cost standpoint, companies understandably strive for economic efficiency — i.e., to identify the least expensive option that will accomplish the intended technical effect.

It is critical to understand that the FDA regulatory status of the raw material — i.e., the clearance or exemption upon which a company relies — determines, to a large extent, whether substitutions are permitted when they should become desirable or, in the case of disruptions in the supply chain caused by the novel coronavirus, necessary. From a regulatory perspective, not all food contact substances are treated equally from a substitution standpoint.

Therefore, specific consideration should be given not only to the physical and chemical properties that a particular substance imparts to the finished product, and the relative cost of the material, but also the basis upon which the substance has achieved its suitable FDA status as — or is appropriately exempted from the definition of — a food additive for the intended use.

Under Section 201(s) of the Federal Food, Drug and Cosmetic Act, or FDCA, the term "food additive" is defined, in part, as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of or otherwise affecting the characteristics of any food." Therefore, food packaging, or individual components thereof, including raw materials, may be considered a food additive by indirectly migrating from the packaging to food, unless an applicable exemption applies.

Clearances or authorizations that may be relied upon by any company are generic in nature, and substitutions are generally permitted, subject to applicable limitations discussed below. In contrast, substances that are the subject of proprietary regulatory clearance mechanisms may not be as easily substituted — and the substitution of substances that are the basis of self-determined exemptions or exceptions must necessarily be evaluated on a case-by-case basis.

For each of the regulatory clearance mechanisms identified below, a company should ask and understand: Can a substitution be made?

Generic Food Additive Regulation

Substances that are the subject of a food additive regulation appear in Title 21 of the Code of Federal Regulations. These FDA clearances appear specifically in Title 21 of the Code of Federal Regulations, Parts 170-186, and may be relied upon by anyone.

Companies are permitted to substitute one listed substance for another in the manufacture of a finished food-contact material or article, provided that the substance is listed in an applicable food additive regulation for the intended use. It remains the responsibility of the user of the substance to ensure that applicable compositional and end-test requirements are met, where applicable, and that the material is of a suitable purity for use in food-contact applications.

Importantly, however, substances listed for one specific application generally may not be used in an application not covered by the food additive regulation, unless an applicable cross-referencing provision applies.

Generic Threshold of Regulation Exemption

In 1995, the FDA promulgated its threshold of regulation rule, which provided the agency with the flexibility to exempt certain substances from the need for a specific regulatory clearance under limited circumstances, upon request.

Threshold of regulation exemptions are granted by the FDA on a case-by-case basis, and generally require that: (1) the substance is not a carcinogen (and does not exhibit any unique toxicological concern at low levels in the diet); and (2) the substance is present in the diet at a sufficiently low level when used as intended.

Although threshold of regulation exemption requests are made by specific companies, once authorized by the FDA, they may be relied upon by anyone. Similar to food additive regulations, however, threshold of regulation exemption clearances are limited to the specific intended use described therein, and it remains the responsibility of the user of the substance to ensure that the material is of a suitable purity for use in food-contact applications.

Proprietary Food Contact Notification

The FDA developed its Food Contact Notification, or FCN, program as a more streamlined and efficient manner of evaluating and establishing the suitable status of a food contact substance for a specified use. Under the FCN program, a notifier submits data to the FDA describing the identity, intended use and safety profile of the food-contact substance, as well as certain information demonstrating consistency and control over the manufacturing process.

If the FDA does not object to the notification within 120 days of submission, the FCN automatically becomes effective. Effective FCNs are listed on the FDA's online inventory of effective food contact substance notifications.

The FCN program differs from the food additive regulation and threshold of exemption processes described above in a number of respects. Notably, an FCN clearance is proprietary, and may be relied upon only by the company that submitted the FCN and its customers.

While notifiers enjoy a limited degree of exclusivity with regard to an FCN clearance for this reason, manufacturers of finished food contact materials and articles must exercise caution to ensure that the use of a substance otherwise authorized by an FCN is actually manufactured or distributed by the listed supplier. Because of the proprietary nature of FCNs, companies generally may not substitute raw materials unless the substituted product is also the subject of an FCN, or another applicable clearance or exemption.

In addition, certain food contact substances may be listed in multiple FCNs, but for different applications, use levels, food types and temperature conditions of use. Therefore, specific care and caution should be exercised when relying upon and substituting a food contact substance that is the subject of an FCN.

Self-Determination of No Migration

It is well-established that, if a substance is not reasonably expected to become a component of food under the intended conditions of use, it does not meet the definition of the term "food additive" under the FDCA, and is not required to be the subject of a food additive regulation. The FDA has never specifically defined the relevant criteria or threshold for this so-called no-migration position; therefore, industry relies on various sources of guidance and direction from the historical record to make a self-determination.

Accordingly, each substance must be evaluated on a case-by-case basis, using well-established and internationally-recognized scientific risk assessment principles. A no-migration position must necessarily consider the safety profile of the food contact substance itself, and any impurities and byproducts that may remain available to migrate to food under the intended conditions of use.

A company that relies on a self-determined no-migration position for a substance used in the manufacture of a food contact material or article may substitute a different substance at their discretion, but the replacement substance must necessarily be subject to the same degree of risk and safety assessment as the original substance. Companies should give careful consideration to the potential differences between substances and their replacements, in addition to any impact on the technical suitability and properties of the finished food contact material or article when the replacement is used as intended.

The company should maintain the basis for its no-migration conclusion in its file, whether by way of self-determination or evaluation and assessment by outside counsel, in the event that support for this conclusion is requested by the FDA or the company's customers.

Generally Recognized as Safe: Generic or Self-Determination

Substances that are generally recognized as safe, or GRAS, under their intended conditions of use are exempt from the definition of "food additive" under the FDCA. Section 201(s) of the FDCA defines a GRAS substance as one that is:
generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

Substances that are listed or affirmed as GRAS for direct addition to food appear in Title 21, Code of Federal Regulations Parts 182 and 184 of the food additive regulations. Generally

speaking, and by way of cross-reference, substances that are listed or affirmed for direct addition to food also are considered GRAS when used in food packaging applications.

Separately, companies are permitted to independently determine that their intended use of a substance in the manufacture of food contact materials and articles is GRAS. A GRAS position is a self-determination of fact that is not required to be confirmed by the FDA.

General recognition of safety requires a "common knowledge" that there is a reasonable certainty that a substance is not harmful under the conditions of its intended use. For substances not widely used in food prior to 1958, general recognition based on "scientific procedures" requires the same quantity and quality of scientific evidence as is required to obtain a food additive regulation for the substance.

Companies may rely on GRAS listings and affirmations in Parts 182 and 184, respectively, and generally speaking, may substitute listed and affirmed substances without limitation. Consistent with good manufacturing practice, companies should use only the minimum amount of a GRAS listed or affirmed substance necessary to accomplish the intended technical effect in the finished product.

Companies that rely on a self-determined GRAS position may similarly substitute other substances that also rely on a self-determined GRAS position, but each GRAS position must necessarily be considered and evaluated on a case-by-case basis.

Reasons to Try

To maintain consistency and elasticity in the supply chain, companies should carefully consider the number of raw materials that it has readily available to manufacture food packaging.
Ideally, companies should preemptively establish a suitable FDA regulatory basis for concluding that one or more alternative(s) may be used as intended.

The incremental cost associated with the availability of the alternative may well offset the cost of future supply chain disruptions. The economic consequences of years of cost minimization-based decision making in manufacturing became readily apparent when the unexpected shock of the novel coronavirus impacted the supply chain across entire industries.

To avoid a similar situation in the future, companies should avoid cost minimization as the sole basis for decision-making, and instead consider adopting a different economic concept — the efficient frontier — as an alternative with regard to raw material alternatives. That is, companies should seek to identify a reasonable balance between maintaining a suitable number of raw materials that will ensure a sufficiently high degree of elasticity in the supply chain, and the incremental costs of establishing a suitable FDA status for each.

Companies that are willing to identify and try alternatives while things go right will benefit greatly the next time that things go wrong, and the exercise of identifying alternatives will continue to drive food packaging product innovation for years to come.

Daniel C. Rubenstein is an associate at Steptoe & Johnson LLP.

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