McGUIREWOODS

MEMORANDUM

TO: FOOD MARKETING INSTITUTE
Stephanie K. Barnes, Chief Regulatory Officer & Legal Counsel
Dana Mullen Graber, Regulatory Counsel

FROM: **Laura Dougherty Venker**, Associate — Office: 202.857.2447
lvenker@mcguirewoods.com — Mobile: 757.532.0782

Angela M. Spivey, Partner — Office: 404.443.5720
aspivey@mcguirewoods.com — Mobile: 404.606.0500

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RE: Best Practices in Supply Chain Agreements | Recalls and Market Withdrawals

The purpose of this memorandum is to address best practices in supply chain agreements with respect to the allocation of liability in the event of a recall or market withdrawal.

The examples set out in this document are intended to function as starting points for discussions between the contracting parties. Like a supply chain, the elements of a Supply Agreement relate to one another in complex and sometimes unanticipated ways. As such, every Supply Agreement should be evaluated as a whole to ensure that, once the Agreement is in operation, provisions related to recalls and market withdrawals will operate as intended.

I. Background

A *market withdrawal* occurs when a firm removes or corrects a distributed product that has a minor violation that would not be subject to FDA legal action or which involves no violation (e.g., normal stock rotation practices or a quality issue).[1]

A *recall* occurs when a firm removes or corrects a marketed product that FDA considers to be in violation of the laws FDA administers and against which FDA would initiate legal action.[2] FDA may also issue a mandatory recall order if a company fails to cooperate with FDA's request to conduct a voluntary recall.[3]

However, FDA can take a number of actions other than, or in addition to, ordering a mandatory recall, as can other federal, state, and local agencies. Independently or in concert, these actions may affect the marketability of the products at issue, as well as the liability that may attach to distributing the products.

[1] 21 CFR § 7.3(j).
[2] 21 CFR § 7.3(g).
[3] 21 U.S.C. § 350l.

The recent *E. coli* O157:H7 infections which FDA describes as "likely linked" to romaine lettuce from the Yuma growing region provide an example of the escalating measures FDA and other agencies may take to inform and advise affected parties of the potential public health concern.[4]

The FDA maintains a webpage devoted to "Recalls, Outbreaks, & Emergencies,"[5] and the Centers for Disease Control (CDC) maintains a page that covers outbreaks of both foodborne illness and other infectious diseases.[6] Both agencies allow users to subscribe to receive emails regarding updates to these pages, and each maintains a number of official Twitter accounts which they can use to share news relating to recalls and outbreaks. States and localities also issue statements providing information, advice, warnings, or notices of outbreaks, recalls, public health concerns, or on-going investigation.[7] All of the statements described below were posted on the respective Agencies' websites, alerted to subscribed users, and publicized via the Agency's Twitter accounts.

One of the most innocuous public actions FDA takes is to release an informational statement,[8] indicating that, together with the CDC, and typically state, local, and sometimes international partners, it is investigating an outbreak, but there is no action for any outside party to take at that time.[9] In the case of *E. coli* O157:H7 infections associated with leafy greens which sickened people in late 2017, at the same time FDA informed the public of its investigation, it also indicated that the "suspect leafy greens linked to this outbreak are likely no longer in the food supply," thereby allaying, at least in part, both consumer concern regarding the consumption of leafy greens, and supply chain responsibility for continuing to distribute leafy greens. Two weeks later, the CDC announced that the outbreak "appeared to be over," and the following month, FDA announced it had ended its investigation (without identifying a common supplier, distributor, or retailer).[10]

When FDA feels an outbreak merits greater attention due to an on-going health risk, it will release a statement of investigation,[11] alerting stakeholders to an investigation, as well as actions that retailers, restaurants, other food service operators, and consumers should take to protect public health. In the case of the on-going investigation into romaine lettuce from the Yuma growing region, FDA has stated that "[c]onsumers should…not eat or buy any romaine lettuce from the

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[4] The Center for Food Safety and Applied Nutrition was the first FDA-related account to Tweet on the matter on April 13, 2018: https://twitter.com/FDAfood/status/984885562095136769. The CDC sent its first Tweet the same day (https://twitter.com/CDC_NCEZID/status/984856217246986240) and has been issuing regular updates, including one sent on May 14th, not to "eat or buy ANY type of #romaine lettuce unless you can confirm it is not from the Yuma, Arizona growing region": https://twitter.com/CDC_NCEZID/status/996065356820238336.
[5] Available at https://www.fda.gov/Food/RecallsOutbreaksEmergencies/default.htm.
[6] Available at https://www.cdc.gov/outbreaks/index.html.
[7] *See, e.g.*, Arizona Dept. of Health Services, "ADHS advises residents to not eat and throw away chopped Romaine Lettuce," April 13, 2018, https://ein.az.gov/emergency-information/emergency-bulletin/adhs-advises-residents-not-eat-and-throw-away-chopped; Graham County, Arizona, "Multi-State E. Coli Outbreak," April 2018, http://www.graham.az.gov/multi-state-e-coli-outbreak/.
[8] This term is used for ease of reference only. FDA does not consistently use a specific term for this type of publication.
[9] "FDA Information about E. coli O157:H7 Outbreak Likely Linked to Leafy Greens," Jan. 10, 2018, https://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm591989.htm.
[10] "FDA Ends Investigation of E. coli O157:H7 Outbreak Likely Linked to Leafy Greens," Feb. 28, 2018, https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm593896.htm.
[11] This term is used for ease of reference only. FDA does not consistently use a specific term for this type of publication.

Yuma growing region" and "[r]etailers, restaurants, and other food service operators should not sell or serve any romaine lettuce from the winter growing areas in the Yuma region."[12] If the source of romaine lettuce cannot be confirmed, consumers are directed not to eat it and businesses not to sell or serve it.

The CDC also acts to protect public health in the event of foodborne illness outbreaks. CDC will issue advisory statements,[13] which identify actions consumers, restauranteurs, retailers, and clinicians should take. In its advisory statement on romaine lettuce from the Yuma growing region, CDC advises consumers "not [to] eat or buy romaine lettuce unless you can confirm it is not from the Yuma growing region" and restaurants and retailers "not [to] serve or sell any romaine lettuce unless you can confirm it is not from the Yuma growing region. This includes whole heads and hearts of romaine, chopped romaine, baby romaine, organic romaine, and salads and salad mixes containing romaine lettuce."[14] CDC also advises that restaurants and retailers "ask their suppliers about the source of their romaine lettuce."

II. Allocating Financial Liability for Recalls, Withdrawals, and in the Wake of Agency Advisory Statements

One of the most critical factors in a successful supply chain agreement – both with respect to its negotiation and enforcement – is to reach a meeting of the minds, including as to which party bears financial liability if the product is implicated in a recall, market withdrawal, or agency advisory statement.

As an example, a Buyer might agree to a provision whereby the Supplier bears the financial burden only if the product is recalled – a relatively Supplier-friendly provision – in exchange for more favorable pricing terms. If the Buyer uses the Supplier's ingredient in a processed product, and necessary processing eliminates both safety and quality issues that might otherwise arise, however, this seemingly Supplier-friendly provision may be equally Buyer-friendly.

In contrast, a Buyer of a commodity especially susceptible to being a vector for foodborne illness might insist on provisions that protect the Buyer if any federal or state agency issues a statement advising that consumers not eat or businesses not sell the commodity or items containing the commodity. The 'insurance' provided to the Buyer with this approach should be reflected in the Supplier's price – since the Supplier is providing not only the product, but insurance with it. If the Supplier has already invested in a robust food safety and traceability plan, however, the Supplier's price may already reflect the value of an item the Supplier is prepared to stand behind, regardless of issues that might arise in the market. If so, offering the Buyer-friendly provision may allow Supplier to attract more Buyers than might otherwise be the case.

In the subsections below, we provide practice tips for achieving either of these outcomes, as well as providing protection for a Buyer when the Supplier's product is out of specification.

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[12] "FDA Investigating Multistate Outbreak of E. coli O157:H7 Infections Likely Linked to Romaine Lettuce from Yuma Growing Region," May 9, 2018, https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm604254.htm.

[13] This term is used for ease of reference only. CDC does not consistently use a specific term for this type of publication.

[14] CDC, "E. coli O157:H7 Infections Linked to Romaine Lettuce," May 9, 2018, https://www.cdc.gov/ecoli/2018/o157h7-04-18/advice-consumers.html.

A. Supplier Responsible for Recalls Only

If the parties wish for the Supplier to be financially responsible for a product recall, the Supply Agreement should include provisions stating that if a federal, state, or local agency requests or orders a recall, the Supplier will:

- fully cooperate with Buyer, at Supplier's sole expense, to effect the recall, including determining the source and scope of the issue and the location of affected product; and

- reimburse Buyer for losses, damages, costs, and expense incurred by Buyer in connection with the recall.

B. Supplier Responsible if an Advisory Statement is Issued

If the parties agree that the Supplier will bear financial responsibility for a market withdrawal if any federal, state, or local agency issues an applicable "advisory statement," it is critical to clearly specify in the Agreement what agency actions the parties wish to encompass. For example, the parties might agree that Tweets, on their own, are not advisory statements, nor are posts made on an Agency's blog, but any other statement published on an Agency's website or transmitted via the Agency's email account would constitute an advisory statement, provided the statement actually cautions, warns, directs, instructs, or otherwise advises consumers not to consume, or retailers, restauranteurs, food processors, or other entities responsible for manufacturing, processing, distributing, or serving food not to distribute, sell, or serve a specific food or type of food.

Because the scope of an advisory statement is frequently geographically limited, and because the Supplier is better positioned than the Buyer to document the source of the goods, we recommend that the provision be framed to require the Supplier to document that the product is <u>not</u> within the scope of the advisory, rather than place the burden on the Buyer to prove that the product <u>is</u> within the scope of the advisory.

As an example, a Supply Agreement might state that, if, on demand from the Buyer, the Supplier cannot document that the supplied product does not fall within the scope of an Advisory Statement, the Supplier will:

- fully cooperate with Buyer, at Supplier's sole expense, to effect a market withdrawal, including determining the source and scope of the issue and the location of affected product; and

- reimburse Buyer for losses, damages, costs, and expense incurred by Buyer in connection with the withdrawal.

To the extent that less than 100% of the product provided by Supplier falls within the scope of the Advisory Statement, if the Supplier can segregate affected product (and can document that the remaining product is not within the scope of the Advisory Statement), Supplier's liability should be limited to the affected product.

C. Supplier Responsible for Other Market Withdrawals

Few Suppliers will agree to accept financial responsibility if the Buyer unilaterally decides to remove a product from the market because the product has "a minor violation that would not be

subject to FDA legal action" (*i.e.*, if the Buyer conducts a market withdrawal). However, in the course of business, Suppliers regularly accept financial responsibility for providing goods that are found to be outside the Buyer's specifications.

Buyers can therefore secure the Supplier's commitment to bear financial responsibility for a market withdrawal if the Buyer's conditions for conducting a market withdrawal are written into the Buyer's specifications. The Supplier would then guarantee, through provisions in the Supply Agreement, to provide product that meets Buyer's specifications and to:

- fully cooperate with Buyer, at Supplier's sole expense, to effect a market withdrawal, including in determining the source and scope of the issue and the location of affected product, if product is found to be outside the Buyer's specifications; and

- reimburse Buyer for losses, damages, costs, and expense incurred by Buyer in connection with the withdrawal.

III. Other Practice Tips

- **Definition of costs**: For the avoidance of doubt, we recommend the parties specify how "losses, damages, costs, and expense" will be defined. For example, for purposes of the Supply Agreement, the cost of goods could be defined as:

  - the Buyer's cost of goods sold;

  - replacement cost of the goods;

  - whichever is greater; or

  - whichever is less.

  Handling, freight, warehousing, and other loading, transportation, and storage costs or expenses incurred by the Buyer in connection with the recall are typically encompassed in the Buyer's "losses, damages, costs, and expense," but it is prudent to specify this. It is less common for the Supplier to reimburse the Buyer's administrative and legal costs, so if this is the parties' expectation, it should certainly be stated.

- **Products not yet in distribution**: Because of how the term 'recall' is defined in regulation, products that have not yet reached distribution cannot meet the definition of a recalled product. As such, it is important to ensure that any provisions assigning financial liability for recalled goods is written to encompass products that, if distributed, would be subject to recall – provided that is the parties' intent at the time of contracting. The same is true for market withdrawals – if the product never reaches market, it is not being withdrawn from market, even if the end result – that it is deemed unsaleable due to a quality issue, for example – is the same.

- **Indemnification**: An indemnification provision – by which the Supplier guarantees it will defend, indemnify, and hold the Buyer harmless against specified claims – should accurately reflect the parties' intentions as to the scope of the protection Supplier is providing to Buyer. This is especially true if, given the nature of the commodity and supply

chain, a recall or withdrawal that affects Buyer or Supplier is likely to trigger claims from downstream customers.

- **Insurance**: The Supplier's guaranty to reimburse in the event of a recall, advisory statement, and/or out-of-specification product should be supported by appropriate insurance policies. Appropriate policies and policy amounts will vary depending on the circumstances.

- **Terms of reimbursement**: We recommend that the agreement set out terms of payment (*e.g.*, "to be paid to Buyer within ten days by ACH or any other method of payment Buyer deems acceptable") and specify whether Seller may offset its liability against past or future amounts due from Buyer.

IV. Final Thoughts

Among the many issues that cannot be addressed in a document of this type are product- and process-specific matters, but these should be considered before a Supply Agreement is signed. A few of the many factors to consider when negotiating include whether the product would be especially difficult to replace if an outbreak affected the commodity (*e.g.*, it is available only from a limited geographic region, its region of origin is an important element of the product's marketing, it has a short growing season); whether the product is more expensive to replace during certain times of the year; and whether new labeling would be needed if the product were replaced (*e.g.*, because the product was sourced from a different country than its original source).

Finally, although not directly tied to the negotiating process, both Buyers and Suppliers should consider whether their current traceability plan, as implemented, would allow them to appropriately limit the scope of a recall or withdrawal. The most Buyer-friendly Supply Agreement will not protect the Buyer if the scope of a recall or withdrawal is unnecessarily broad because the Buyer did not implement an appropriate traceability plan.

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