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## Lawsuit May Impact FDA Food Recall Authority (/full-blog/2011/10/lawsuit-may-impact-fda-food-recall.html)



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By: Colby Khoshreza, Staff Member

A recent legal action by a major fruit company against the Food and Drug Administration (“FDA”) could have a significant impact on regulators’ efforts to monitor and recall unsafe foods. A lawsuit filed by the Florida-based Del Monte Fresh Produce challenges an FDA alert regarding imported cantaloupes from Guatemala.[1] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_edn1](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_edn1)) This suit comes on the heels of recent legislation that increased FDA authority in the area of food regulation.

Prior to the litigation, the FDA linked Del Monte cantaloupes to at least 12 cases of salmonella poisoning.[2] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_edn2](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_edn2)) Del Monte issued a voluntarily recall; however, the FDA moved forward with an import alert that halted imports of the cantaloupes from Guatemala. [3] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_edn3](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_edn3)) In their lawsuit, Del Monte claims that FDA officials based their decision on an “erroneous speculative assumption, unsupported by evidence.”[4] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_edn4](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_edn4)) Del Monte has also cited failures by the local department of health in gathering evidence.[5] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_edn5](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_edn5)) The company claims that the farm targeted by the alert produces nearly one-third of the cantaloupes that Del Monte imports.

This dispute is especially interesting in light of recent legislation that provides the FDA with increased regulatory authority over food. In January, President Obama signed the Food Safety and Modernization Act (FSMA S.510), which provides the Food and Drug Administration with increased authority over food monitoring.[6] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_edn6](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_edn6)) The FSMA gives the FDA, for the first time in its history, the authority to issue mandatory recalls as well as a host of other powers including the ability to refuse food imports when a foreign facility refuses to submit to an inspection. [7] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_edn7](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_edn7))

While the impact that this lawsuit may have on overall FDA food regulation is still unknown, it is likely to cause regulators to become more relaxed in their issuance of recalls and warnings. Lawsuits are seen as having a chilling impact on regulation in general; in regards to the FDA, the result is likely to be more cautious regulation. While unhappy food producers may not like the FDA’s increased authority over food monitoring, it is the responsibility of the agency to keep consumers safe. Lawsuits are inevitable but the focus must remain on consumer health.

Prior to the passage of FSMA S.510, the FDA had been widely criticized for not taking strong enough action to protect consumers. However, it is likely that much of the criticism aimed towards the FDA occurred as a result of its limited powers - such as not having the authority to implement mandatory food recalls. The new legislation is aimed to give the FDA the necessary regulatory strength to keep the public safe.

In light of the new legislation, this lawsuit could potentially have two distinct outcomes on the FDA’s regulatory authority. On one hand, the FDA may step up its regulatory reach as a result of being given more authority to combat uncooperative companies and ensure higher levels of safety. The other and more likely outcome is that the FDA will be more cautious in its regulatory efforts. While it is not unreasonable for the FDA to proceed with caution in its regulation - there is much at stake when they issue recalls and warnings - the agency should remain focused on protecting consumers. In expanding its powers, Congress clearly wanted the FDA to stand firm and to provide stronger public protection in the areas of food production and consumption. Lawsuits will come and go; the public’s expectation to be protected will not.

[1] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_ednref1](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_ednref1)) Mary Clare Jalonick, *Lawsuit Could Chill Government Efforts to Keep Food Safe*, KGW (Sept. 1, 2011, 8:52 AM), <http://www.kgw.com/lifestyle/health/Suit-could-chill-govt-efforts-to-keep-food-safe-128886048.html> (<http://www.kgw.com/lifestyle/health/Suit-could-chill-govt-efforts-to-keep-food-safe-128886048.html>).

[2] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_ednref2](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_ednref2)) Marion Nestle, *Don't Like Bothering Food Safety Rules? Sue the FDA!*, FOOD POLITICS (Aug 30, 2011), [http://www.foodpolitics.com/2011/08/don't-like-bothering-with-food-safety-rules-sue-the-fda/](http://www.foodpolitics.com/2011/08/don-t-like-bothering-with-food-safety-rules-sue-the-fda/) (<http://www.foodpolitics.com/2011/08/don%27t-like-bothering-with-food-safety-rules-sue-the-fda/>).

[3] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_ednref3](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_ednref3)) Mary Clare Jalonick, *Lawsuit Could Chill Government Efforts to Keep Food Safe*, KGW (Sept. 1, 2011, 8:52 AM), <http://www.kgw.com/lifestyle/health/Suit-could-chill-govt-efforts-to-keep-food-safe-128886048.html> (<http://www.kgw.com/lifestyle/health/Suit-could-chill-govt-efforts-to-keep-food-safe-128886048.html>).

[4] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_ednref4](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_ednref4)) *Id.*

[5] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_ednref5](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_ednref5)) *Id.*

[6] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_ednref6](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_ednref6)) Food Safety and Modernization Act, 21 U.S.C. § 2201 (2011).

[7] ([http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#\\_ednref7](http://www.kjeanrl.com/search?updated-max=2011-11-18T11:00:00-05:00&max-results=7&start=21&by-date=false#_ednref7)) *Id.*

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