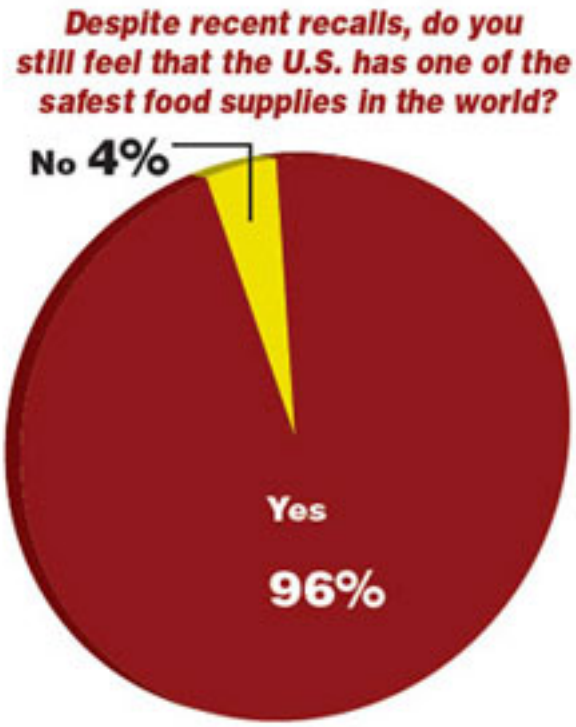
Regulatory Compliance: More Trouble than it's Worth?



The large number of recalls in recent history has caused consumers to doubt the safety of our food supply as well as stimulated scrutiny of regulatory agencies in the food industry. While FDA and USDA guidelines, policies and inspections are devised to ensure the safety of our nation's food supply, they still can be a source of frustration and confusion within the food industry, and their efficacy is sometimes called into question.

In fact, in a recent survey of Food Manufacturing readers, 35 percent of respondents cited interpretation of rulings and policies of agencies (such as the FDA, USDA and EPA) as their plant's biggest obstacle when it comes to regulatory compliance. Keeping up to date on new regulations was noted as the biggest obstacle by 28 percent of food manufacturers, followed by costs associated with regulatory compliance (20 percent).

When asked which specific regulations presented the largest challenge, 33 percent of food manufacturer's pointed to regulations related to product labeling. This result is not surprising in the wake the recent FDA crackdown on deceptive food labels and packaging. In addition:

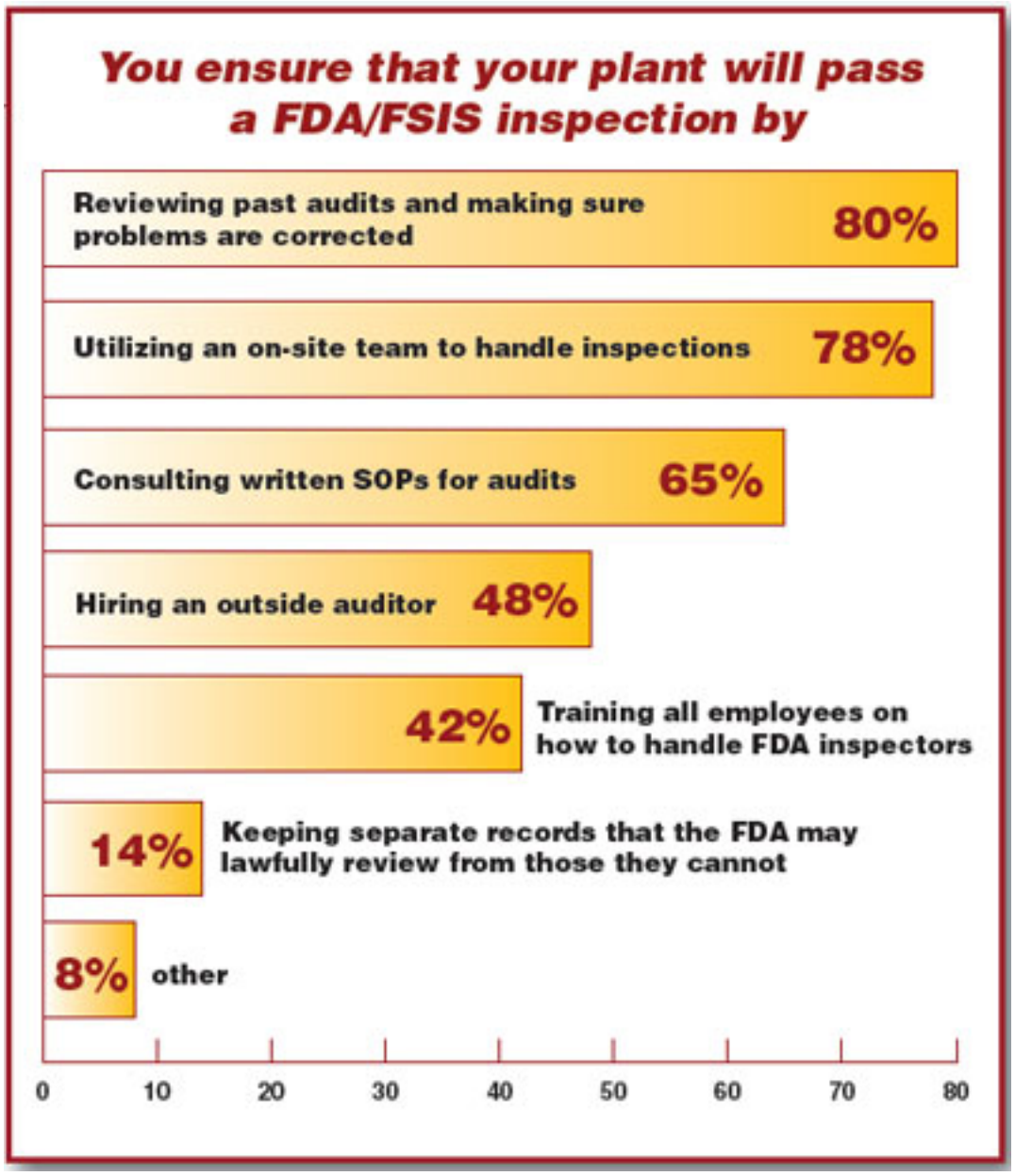
- 27 percent struggle with sanitation-related regulations
- 25 percent with HACCP-related regulations
- 22 percent with pathogen-related regulations

- 20 percent with regulations related to air/environmental standards
- 18 percent with equipment certification-related regulations
- 17 percent with ingredient-related regulations
- 16 percent with import-related regulations

As food manufacturers work to overcome their regulatory compliance obstacles, regulatory agencies are facing struggles of their own. The FDA's Food Protection Plan (November 2007) focused on a three-pronged initiative for increased food safety: prevention (promoting increased corporate responsibility so that food problems do not occur in the first place), intervention (risk-based inspections, sampling and surveillance at high risk points) and response (communicating[k1] clearly with consumers and other stakeholders during and after emergencies). According to survey results, 56 percent of food manufacturers feel that the FDA's biggest weakness lies in its prevention efforts. 33 percent are concerned about the FDA's intervention initiatives, while 11 percent feel that the FDA's response is its largest weakness.

So what is causing these weaknesses? According to 52 percent of surveyed manufacturers, a lack of manpower is the biggest hindering factor for the FDA. The severe lack of food safety inspectors has left government agencies reacting to food safety issues rather than preventing them. Lack of funding was cited as the biggest hindrance to efficacy by 23 percent of respondents, while 21 percent blamed the agencies' lack of power to enforce rules and 3 percent blamed a lack of access to specific plant information.

In terms of the FDA and USDA's enforcement power, many critics feel that the fact that government agencies cannot force a food company to recall its products is a serious detriment to food safety. However, given that the food industry is already prepared to take responsibility for the safety of its products, the industry does not appear to be threatened by impending legislation that would give the FDA mandatory recall authority. For example, Georgia lawmakers are currently considering a food safety bill that would make it a felony to knowingly distribute a tainted food product, and violators could face up to 20 years in prison plus a $20,000 fine. 72 percent of survey food manufacturers felt this law is a necessary measure.



Additional efforts that the food industry would like to see undertaken by regulatory agencies in order to improve oversight of food products include:

- 74 percent would like to see FDA inspections in plants that export to the U.S.
- 53 percent want federal agencies to share information on a global level
- 44 percent would like to see U.S. safety inspectors placed around the world to ensure the safety of imports
- 40 percent would like to see an increased FDA/USDA presence in U.S. food plants
- 40 percent want to give the FDA/USDA enhanced access to food records during emergencies

Plant managers, knowing that they cannot rely on regulatory agencies alone, understand their plants' vital role in food safety. While it is important to mention that many survey respondents pointed out that plants should always be audit-ready, they also indicated several key action steps that can be used to ensure that

plants are ready for FDA/USDA inspections, including utilizing an onsite team to handle inspections, consulting written SOPs for audits and reviewing past audits to make sure problems were corrected. The latter was a major point of contention during the 2009 Peanut Corp of American recall because during the recall details of numerous unresolved product quality and plant inspections violations emerged.

Despite recent recall woes and varying opinions on government regulations, the industry's future outlook is somewhat positive, as 96 percent of surveyed food manufacturers – arguably those getting the closest look at the safety of the food supply, as well as being consumers with families of their own to feed – still assert that the U.S. has one of the safest food supplies in the world.

Source URL (retrieved on *09/18/2014 - 7:57pm*):
http://www.chem.info/articles/2010/06/regulatory-compliance-more-trouble-its-worth?qt-most_popular=1