

## Food Packaging Equipment – FoodPack Company Foreign Compliance Case Study, May 2017 (Company Name Changed to Protect Confidentiality)



### BACKGROUND

FoodPack designs and manufactures a full line of food industry packaging and processing equipment for the meat, poultry, seafood, baking, pasta, and cheese segments. Its machines have standard options, but can also be customized, a key point with regard to compliance. It has roughly 48 employees, with international representing between 5 and 25% of total sales. Over the years, FoodPack has sold into 12-14 different countries.

### EUROPEAN MARKET

FoodPack got its first CE Mark roughly 15 years ago for its flagship machine. It worked with a U.S. based testing and compliance company, which is also an approved CE Testing Laboratory and an EU Notified Body (an organization designated to certify compliance with European regulations). This testing and compliance company helped with the certification process, the technical manual, emissions testing, and development of the risk assessment. FoodPack claims that it “lived off [that CE Mark] for years, and never had questions or issues...”

Since 2002, FoodPack has also worked with a 2<sup>nd</sup> U.S. based company for testing and documentation to certify additional machines. Over the years, standards have changed – with risk assessment having become particularly complex and comprehensive. FoodPack hasn’t had to change its products as a consequence, but additional documentation for the risk assessment standard has been necessary. FoodPack has also employed a 3<sup>rd</sup> testing company specifically for EMC/EMI testing.

Each EU country has specific “twists” on the European requirements. At one point, FoodPack had a distributor located in the Netherlands. The distributor adapted FoodPack’s CE marked machines as needed for specific country or customer requirements. But since separating from that distributor, FoodPack primarily sells direct to food processors. Consequently, FoodPack is now responsible for compliance with country-specific requirements, because it is no longer “buffered” by the distributor. FoodPack’s strategy has been to focus on compliance with the Machinery Directive (which is probably the most important set of requirements for their equipment).

Affixing the CE Mark declares conformity with all applicable directives and standards, including the EU Machinery Directive. And it is extremely challenging to understand and conform to all these requirements, *and* adapt to the specific “twists” required by each EU country. Recently, FoodPack had an issue with a French customer, which illustrates these challenges. The customer wanted modifications to the safety guards on the machine, and suggested that it was a compliance requirement. FoodPack believed it was in compliance with the general Machinery Directive, and asked the customer and the French certification body to cite the relevant standards that required modification of the guards. The French certification body was assessing the machine’s conformity with 28 applicable directives and standards, and their team could not identify the specific standard that required changes to the guards. As a result, the modification became a customer request, and was paid for by the customer.

## OTHER MARKETS

In Canada, CSA (Canadian Standards Association) compliance has not been a major barrier for the company. In the past, FoodPack sold direct to end-users who would work with the company on compliance. The customer might send an engineer to FoodPack and together they would make minor adjustments to the product to conform with regulations. Or, in the case of one specific Canadian customer, FoodPack sold machines that were compliant with US standards and the customer assumed responsibility for Canadian compliance. Alternatively, in some cases, FoodPack sold equipment that was compliant with generic CSA standards, and the customer was responsible for compliance after making any modifications.

More recently, FoodPack has experienced new compliance challenges related to Ontario, Canada's PSR (Pre-Start Health and Safety Review regulation). Before a worker can operate new or modified machinery or equipment, an "employer is responsible for ensuring that a thorough report is prepared that shows that the equipment is safe. This PSR report is required to review all of the relevant regulations pertaining to that particular type of equipment."<sup>1</sup> PSR is the responsibility of the *employer* of the machine operator not the *manufacturer* of the machine. (For example, it is not illegal to sell a non-PSR-compliant machine but it is illegal for an employer to have a worker use a non-compliant machine.) However, in Ontario, PSR responsibility is being pushed upstream onto the manufacturer. For FoodPack, the PSR-related modifications have been relatively minor (such as putting properly sized holes in the machine guard that are large enough for washing the machine, but not large enough for a hand to fit through it) and the company has not needed outside assistance with the regulation.

## OTHER STANDARDS

In terms of sanitary design regulations for food equipment, FoodPack indicated that if the equipment meets US standards (i.e. is USDA "accepted"), it is usually compliant in other countries - or at least 99% of the way there. Occasionally customers will suggest sanitary design modifications, which FoodPack will consider adopting for its standard product.

Typically, FoodPack does not sell the food contact materials used with its equipment internationally (such as interleaving paper), because the shipping costs are too high to be competitive. But, when it does, the company's suppliers are compliant with international standards. For example, FoodPack's paper mill that ships to the Middle East, is SQF Level 2 Certified (Safe Quality Food program recognized by the Global Food Safety Initiative or GFSI). Its vendor that sells wax paper for interleaving into Canada, is BRC Global Standards certified (also recognized by the GFSI). And its supplier that sells plastic film is AIB Certified. (AIB is an accredited certification body for BRC and SQF 2000 with accreditation pending for FSSC 22000 or Food Safety System Certification.)

## OTHER ADVICE

Overall, compliance is not too onerous for FoodPack at this stage. "Finding a good consultant and lab that has experience with all the different standards in different markets is key. If you have your own engineering department, take what you learn from consultants and bring it back to improve your product."

Even if you are working with a consultant, they suggest to "learn as much as you can on your own about the regulatory requirements you are attempting to satisfy. The consultant may understand the standards, but they do not know your product as well as you do. Your ability to assist and interact with your consultant constructively can only help the process."

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<sup>1</sup> <http://www.safeworkengineering.com/psr-process.htm>