

# Manufacturing & Distribution

## Hygienic Plant Design for Allergen Management

Hygienic plant design creates the ideal environment for effective allergen cross-contact prevention

BY ANDREA TOLU



**D**uring the first three quarters of 2019, allergens were the cause of 40 percent and 30 percent of FDA's and USDA's recalls, respectively, making 2019 a record year for undeclared allergens, according to Stericycle's Product Recalls Index.

"According to FDA data, mislabeling is the leading cause for allergen recalls, but even if we're seeing fewer Class I recalls for cross-contamination, it doesn't mean that sanitation and allergy control is generally good or that the risk is low," says Charlie Kalish, a food safety consultant and trainer who works with businesses on compliance and audit readiness. "There are all kinds of cross traffic and risk for cross-contact in many facilities, and that's a sort of ticking time bomb."

Effective allergen cross-contact prevention is based on different procedures, such as supply chain control, cleaning and sanitation, personnel hygiene practices, and the use of color-coded tools. Hygienic design, however, is what creates the ideal environment for those procedures to be more effective.

### Ideal Facility Design

Hygienic design is often mentioned in relation to equipment and tools. A less

talked about aspect is its application to plant layouts. The ideal facility design for allergen management is conceived with the purpose of separating traffic patterns of allergens and non-allergens at every processing step: storing, handling, processing, and packaging. "If you can minimize the footprint in a plant where you have allergens, then you can do a better job at controlling them. If they're all over your facility, then it's much more difficult," says Mark Morgan, PhD, head of the food science department at the University of Tennessee in Knoxville, and U.S. liaison for the European Hygienic Engineering & Design Group (EHEDG).

In the Food Safety Modernization Act (FSMA) the principle of separation is included in the cGMPs in Title 21 Sec. 117.20, and states that allergen cross-contact may be reduced by (among the other things) separating "location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means." It's up to food businesses to determine what these effective means are.

To what extent allergens should be segregated from non-allergens will depend first on the type of product and its ingredients. "If your product contains powdery allergens that can become air-

borne and travel around, like, for example, wheat flour, then you want to design a facility with an enclosed area for that," says Vicky Waskiewicz, CEO of Safe Food Resources, a food safety training and consulting organization based in Milwaukee, Wisc.

Another factor is how these ingredients enter the facility. "If I'm just bringing products that are enclosed in a metal drum into my warehouse, they're going to need fewer controls than products that come in a paper bag, which may drop and break, spreading flour all over the facility, or be pierced by a fork truck," says Elise Forward, president of food safety consultant firm Forward Food Solutions, based in River Falls, Wisc.

Once you know the risk of cross-contamination associated with your products, you can then decide on the ideal traffic patterns inside the facility. In practical terms, that might mean assigning separate delivery areas, warehouses, and processing lines to allergen-free products and to those containing allergens.

For plants that are still in the design phase, businesses can work directly with their building contractors to incorporate these principles. The project manager within the company "should be some-

body with a keen understanding of how their food is being made, because hygienic design is going to revolve a lot around efficiency,” says Kalish.

### Hygienic Design for Existing Facilities

For existing facilities, the process is more complex. Many plants offer little or no segregation or unidirectional traffic flow, or have separated production lines that share the same area, or even allergen and non-allergen products being processed using the same equipment.

While lack of proper hygienic plant design increases the risk of cross-contamination, refurbishing the facility or building a new one is rarely a realistic solution, as that would be financially unsustainable. The only way to offset the risk is by adding checks, sanitation practices, inspections, and procedures on top of the existing procedures.

A common scenario would be two products with incompatible allergen profiles running on separate but adjacent production lines. “Depending on the particular allergen, I have seen plastic strip curtains going from ceiling to floor, or actual temporary walls being used,” says Waskiewicz. “When conveyors of two different product lines are crossing paths, these are sometimes reconfigured to eliminate opportunities for cross-contact.”

Other solutions would be to upgrade the ventilation system (to deal with airborne particles) or to invest in hygienically designed equipment and tools.

Before adopting any solution, however, it’s still important to know which paths allergens take inside your building. “Knowledge is power, so it would be really helpful for companies to just map out where allergens are going,” says Forward, adding that you could have them come only to certain door ducts, or funnel them. “Even if you’re dealing with an old facility, you still can find other options,” she adds.

A non-negotiable countermeasure, however, will be to increase cleaning and sanitation: “When you don’t have a very good design, that’s the biggest [area] affected. That means you have to sanitize much more frequently,” says Waskiewicz.

Trying to compensate for a non-optimal plant layout isn’t guaranteed to work every time. One issue is cost: “There are

all kinds of quick fixes that you can do but in the long run, they’re going to cost you more,” says Kalish. Additional checks require more time and resources: Increasing cleaning and sanitation needs more manpower, and production output may suffer if lines have to stop more often; temporary walls may have to be replaced eventually, even if they are cleaned often, especially with airborne dry allergens; and while hygienically designed equipment and utilities may cost less than a new facility,

in dollars and cents, to help them make the right decisions,” says Forward. “What is the cost of a recall? What is the cost of capital improvement, and what are the costs of Band-Aid fixes? Even some kind of ballpark will help them, because the cost of a life is never going to be less than that.”

Forward also notes that pathogen management is very well developed, while allergen management is more in its “teenage years.” She thinks allergen manage-

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they’re likely to be more expensive than average.

The other issue is that you may decrease the risk of cross-contamination only up to a point. “You can improve the equipment design and utilities in critical areas, such as pipe work, electrical conduits, and duct work. But other than that, there’s not a lot you can do, because the traffic pattern is always the problem,” says Morgan.

### Risk Versus Profit

If the chances of cross-contamination are still high despite all countermeasures, then the question is whether the risk of a recall is worth the profit coming from that product: “Sometimes there are tough decisions that have to be made where you can’t run products,” says Forward. Temporary fixes may then just leave the two main issues at stake—risks and costs—unsolved. Lowering the risk of cross-contamination costs money. Not lowering it enough is also a cost. Quite often, the problem is that in the latter case, that cost isn’t visible.

“Most people in the food industry are doing their best to protect people, but it comes back to our quality leaders to be able to communicate to upper management the choices that we need to make

ment is often overlooked because there’s little awareness by top management as to how important this is, or the time needed to fully evaluate it. “Often, it’s simply about watching how the warehouse guys move the product from one point to another. Most companies don’t do that because people aren’t paid to stand around and watch, but that’s what’s needed in order to make improvements,” she says.

Kalish notes that most people don’t get into the food business because they want to control allergens, but because they want to make great products and sell them. “They don’t think of factoring allergen management as a cost into their business plan,” he adds.

“There’s a lot of great design and technology out there in trade publications and at conferences, but how many people know about it and how much it costs?” adds Kalish. “I think there’s a big blind spot in the industry. Hygienic design is trending up, but making it affordable and persuading the business community within the food industry that this is something to invest in, is going to be a worldwide priority and one of the biggest challenges.” ■

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