



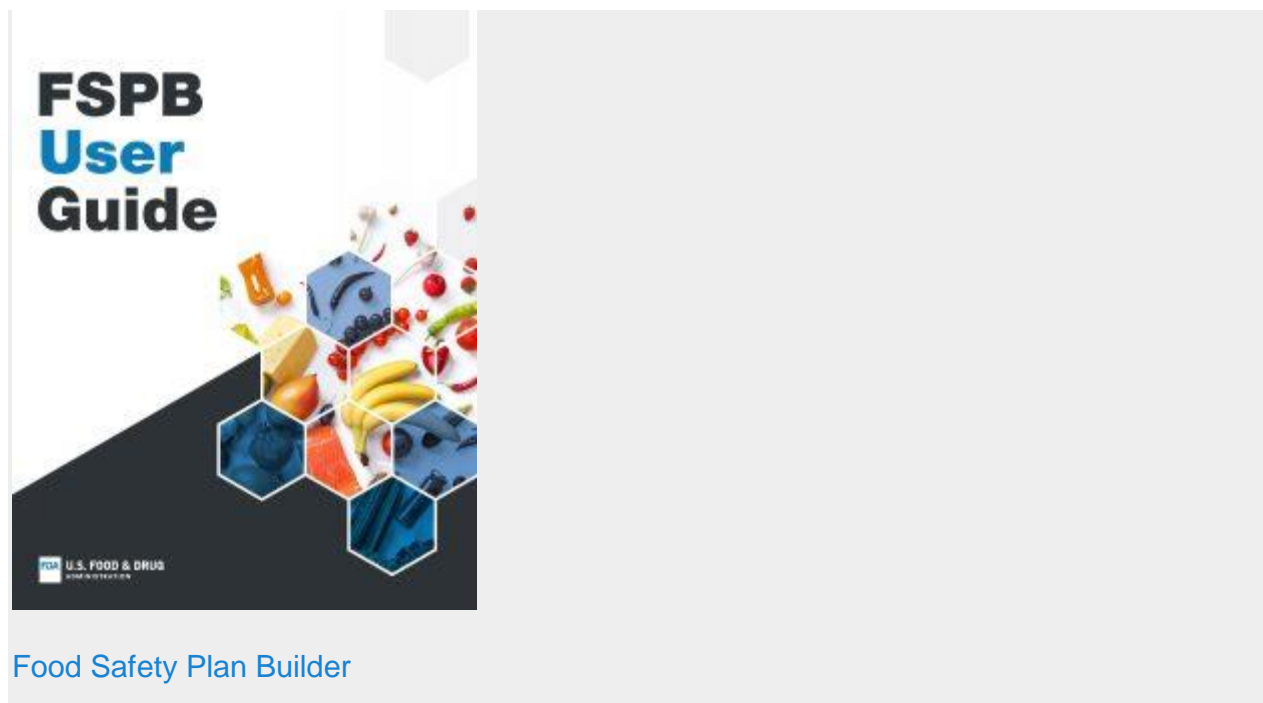
U.S. FOOD & DRUG ADMINISTRATION

Building a Customized Plan to Help Ensure Food Safety

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Every day we evaluate potential hazards in our lives, and take steps to avoid them. We wear our seatbelts. We baby-proof our homes when we have young children. We use passwords to protect secure information online. You might say that when we know hazards exist we put preventive controls in place to protect ourselves.



[Food Safety Plan Builder](#)

Preventive controls – steps taken to reduce or eliminate risk – also are at the heart of the rules mandated by the [FDA Food Safety Modernization Act \(FSMA\)](#). They ask the food industry to approach potential hazards in much the same way that we do in our personal life: identify them and take action to prevent them from harming us.

In September 2015, FDA finalized the Preventive Controls for Human Food rule, which requires owners and operators of food facilities to develop a food safety plan that identifies hazards and puts preventive controls in place to minimize or prevent those hazards. But where should owners and operators start? If they haven't had issues in their facilities before, what should they be looking for? How do they compile their information about hazards and controls in a systematic way?

To help food manufacturers and others comply with these new requirements, FDA is providing a new tool called the [Food Safety Plan Builder](#). This software program can help owners and operators develop customized food safety plans for their facilities. The program can be [downloaded for free](#).

This new tool takes the user through a series of questions that will help identify potential hazards and the preventive controls to have in place to address those hazards. For example, a hazard could be an allergen, like peanuts, and the preventive control could be ensuring that the allergen is properly labeled on the finished product. Another preventive control could be to ensure that the equipment used to process a peanut-containing product is properly cleaned after use to prevent the allergen from contaminating any products that are subsequently processed on the equipment. The food safety plan also must include information about how a facility will ensure that its preventive controls are working, as well as what corrective actions to follow if they are not. Information provided by the user in response to the questions will automatically populate the Food Safety Plan. Users can store the electronic file on their computers or print hard copies if they prefer. The Food Safety Plan Builder is a desktop Windows application that resides only on the user's computer. FDA will not track or monitor use of the Food Safety Plan Builder, nor will it have access to any content or documents developed using this tool. We also have published a User Guide and a series of videos to walk users through how to use the tool.

While use of the FDA's tool is optional, Food Safety Plans are not. Right now, the Centers for Disease Control and Prevention estimates that roughly 48 million people get sick, 128,000 are hospitalized, and about 3,000 people die from foodborne illness each year in the United States. In many cases, these illnesses can be avoided by preventing contaminants from reaching food, and by stopping contaminated food from reaching consumers – exactly what these food safety plans aim to do. Prevention requires us to take a look into the future at what *could happen*, which isn't always easy. That said, both FDA and the food industry have experience in this area. We have seen where things have gone wrong, we have investigated those circumstances, and we have learned from those experiences.

One of our goals at FDA is to educate as we implement FSMA. The Food Safety Plan Builder is part of that commitment to support the partnership we have with the food industry to meet our shared goal of keeping the food supply safe.

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