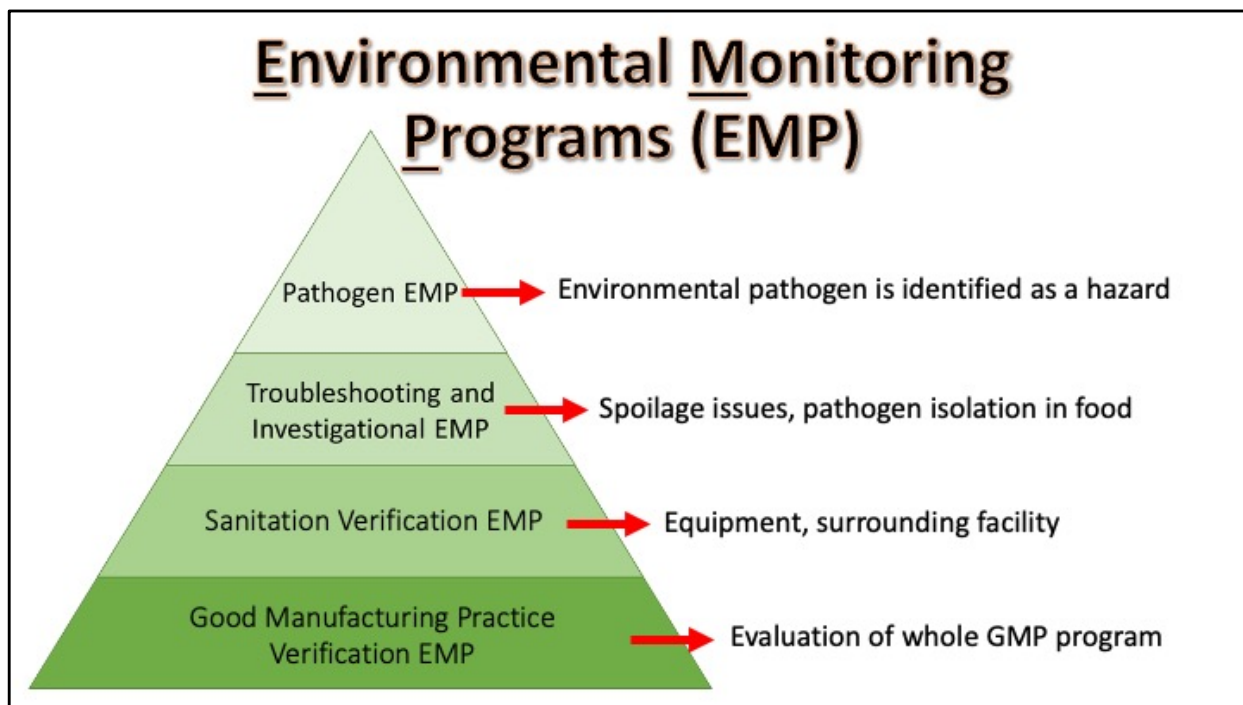




Pathogen Environmental Monitoring Programs: An Introduction



There are several reasons that you might have an **Environmental Monitoring Program** or EMP and each is a little different in purpose and scope.

For example you might want to evaluate or verify your entire Good Manufacturing Practices program. Verify your sanitation program for specific pieces of equipment and perhaps the facility surrounding the equipment

Troubleshooting or investigational EMPs might be used to identify the root cause of a spoilage issue or could be employed after a pathogen isolation in your finished product.

The most specific EMP is the Pathogen Environmental Monitoring Program – this type of program is particularly important when environmental pathogens are a known or reasonably foreseeable biological hazard in your food product.

Objectives for EMP Can Differ

- Evaluate hygienic design of the facility
- Determine if plant maintenance is needed
 - E.g., gaskets or filter change
- Validation/verification of cleaning and sanitation programs
 - Procedures and frequency
- Pathogen detection/elimination
 - Eliminate niches/harborages
 - Known as **Pathogen Environmental Monitoring Programs (PEMP)**

Objectives for EMPs can differ.

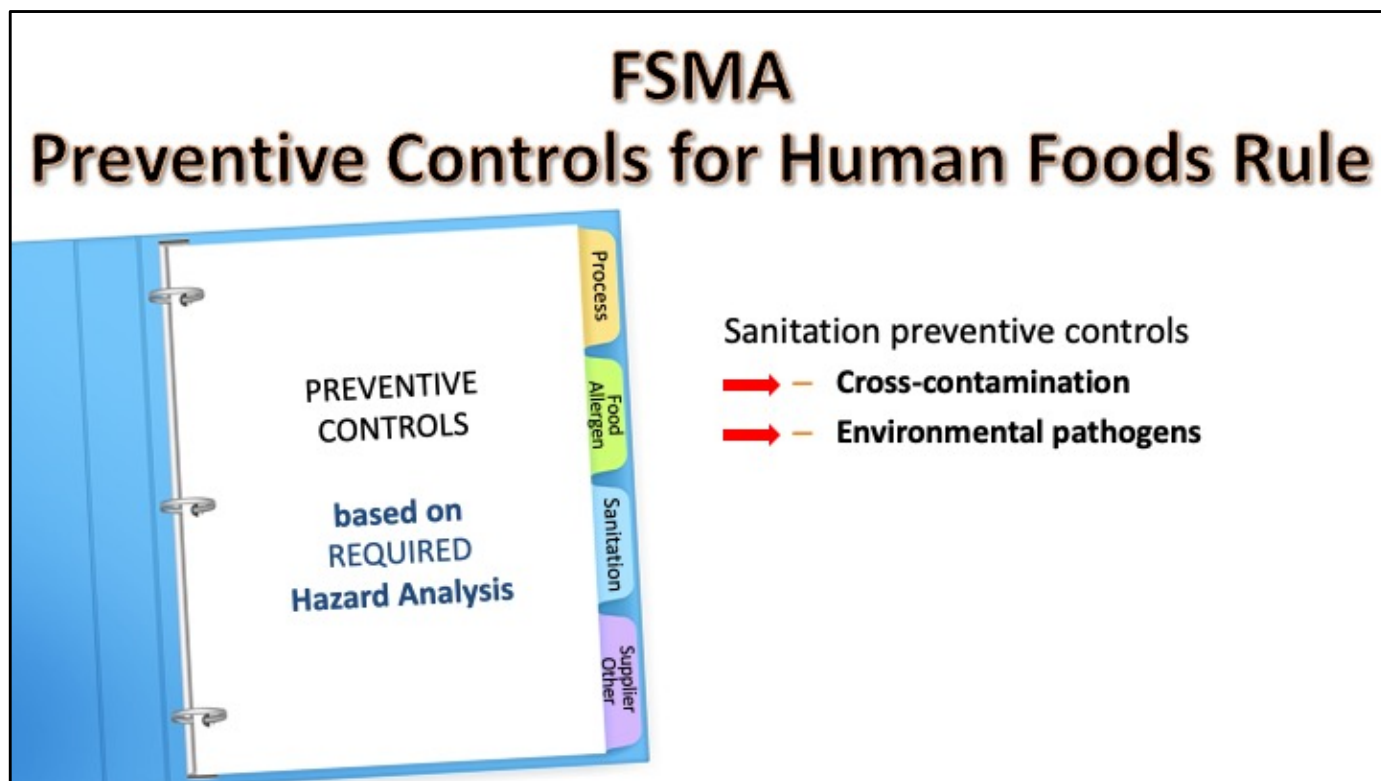
You might use an EMP to evaluate the sanitary design of the facility and to determine how easy is it to keep clean and sanitary.

You might want to use an EMP program to help schedule preventive maintenance such as determining the frequency of gasket or filter changes.

You might use EMP programs to validate or verify cleaning and sanitation programs to document that your procedures and their frequency are adequate and appropriate.

Pathogen detection or elimination is focused on identifying potential pathogen niches and working to prevent pathogens from establishing in the facility.

These are known as Pathogen Environmental Monitoring Programs or PEMPs



Pathogen Environmental Monitoring Programs are covered in the Food Safety Modernization Act (FSMA) or "fizzma" Preventive Controls for Human Foods Rule.

The Rule requires that you establish a food safety plan. One of the first steps in preparing a food safety plan is performing a hazard analysis for each food or food category that is produced in your facility.

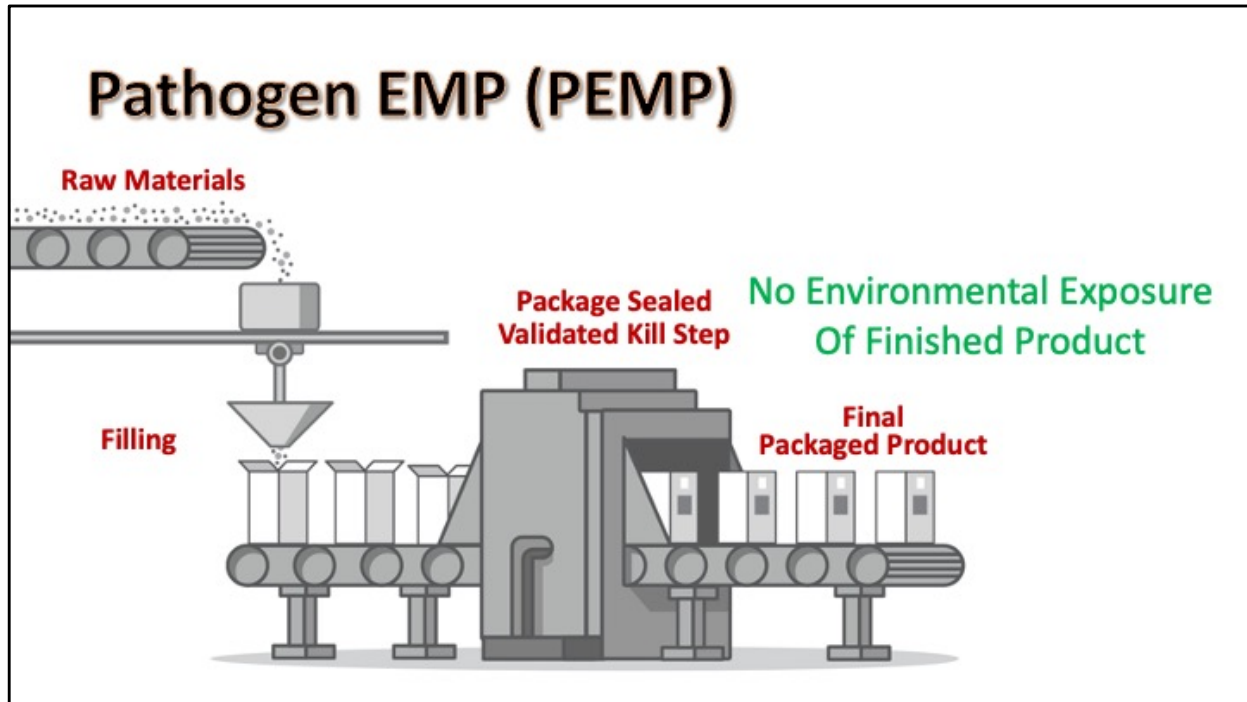
During that hazard analysis you will determine what types of hazards are relevant to your food product and the environment under which it is produced.

*For known or reasonably foreseeable hazards you will need to establish preventive controls. Sanitation preventive controls are designed to reduce or prevent *cross contamination of finished product with biological hazards and prevent the *establishment of environmental pathogens in your facility. In some cases that will require establishment of a PEMP.

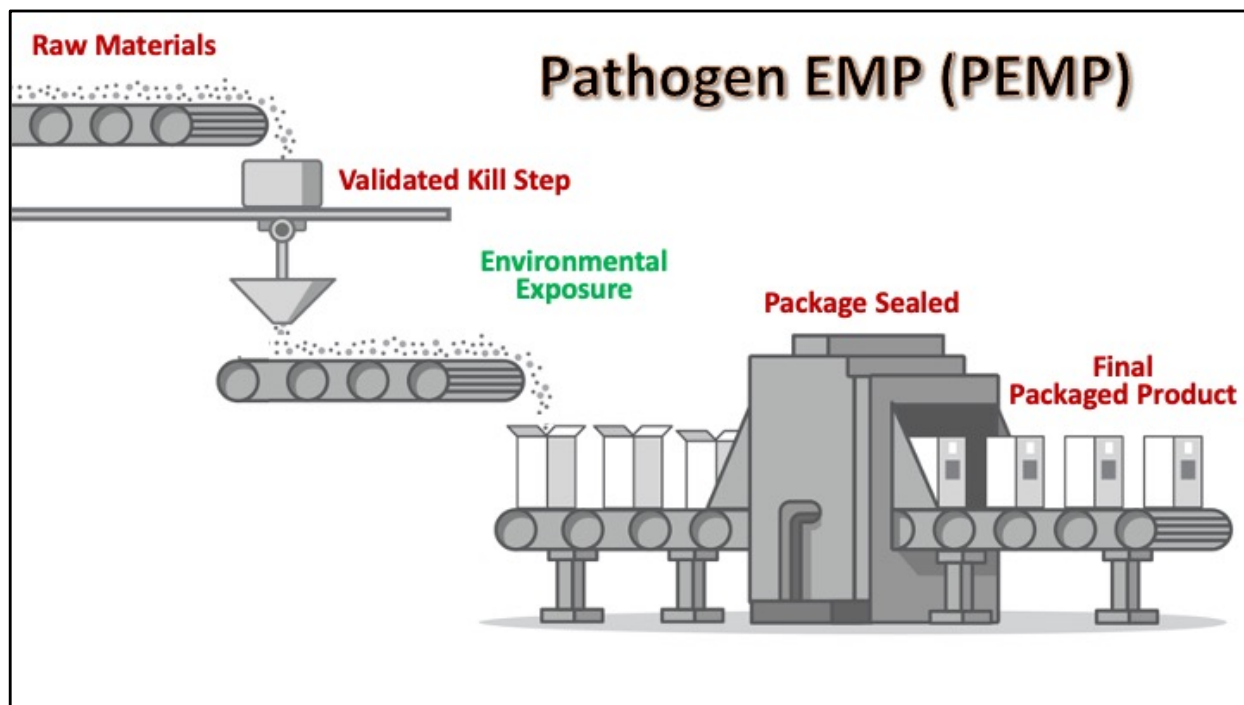
What does FSMA Preventive Controls Rule Say?

- Verification Activity - PEMP
 - Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, **if contamination of a ready-to-eat food** with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples

The Preventive Controls Rule considers PEMPs to be a verification activity for **ready-to-eat foods** that can become contaminated or re-contaminated with an environmental pathogen



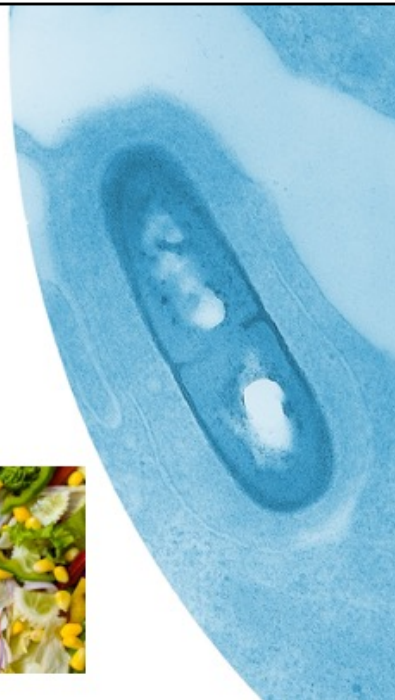
This cartoon provides an example of a ready-to-eat food where environmental pathogens are NOT likely or reasonably foreseeable. In this example the raw materials are mixed together and filled into the final package. The packages are sealed and proceed through a validated cook/kill step or kill step. The key feature of this process is that the finished product is not exposed to equipment surfaces or the processing environment after the kill step is applied. A canned or jarred product that goes into a retort or steam tunnel is an example of this type of food product. In this case a PEMP is not required.



This cartoon provides an example of a ready-to-eat food where contamination with environmental pathogens IS a concern. In this case the raw materials are mixed together and a kill step is applied. The finished product is then exposed to equipment surfaces and the processing environment BEFORE the package is filled and sealed. After sealing, no further kill step is applied. An example of this type of product might be a roasted nut – after the nuts leave the roaster they travel on a conveyer belt while they cool. The final package is then filled with the cooled nuts and the package is sealed. The sealed package doesn't undergo any further processing. In this example a Pathogen Environmental Monitoring program is likely required.

Listeria monocytogenes

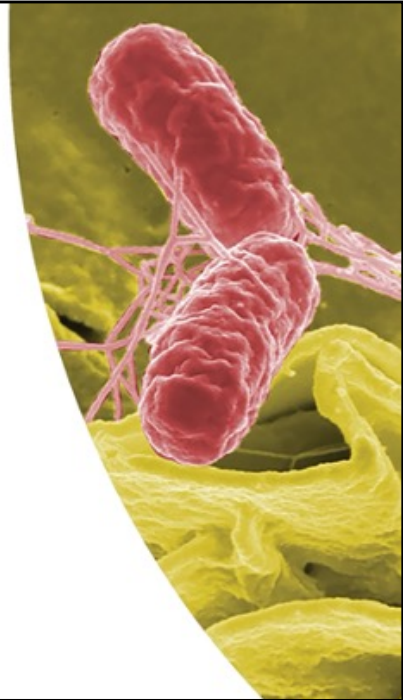
- *Listeria monocytogenes* is the target organism for environmental monitoring of product-contact and non-product contact surfaces in a wet ready-to-eat food manufacturing facility



FDA has identified specific pathogens of concern for environmental contamination based on a history of foodborne outbreaks and product recalls. The ability for a pathogen to establish in a facility is related to the presence of moisture, adequate nutrients, and an appropriate temperature. When foods are high in moisture and are produced in environments where water is used for routine cleaning and sanitation the pathogen of concern is *Listeria monocytogenes*. A large group of foods fall into this category including frozen foods like vegetables, prepared meals, and ice cream, and refrigerated foods such as dairy products, prepared salads, some types of beverages.

Salmonella

- *Salmonella* is the target organism for environmental monitoring of product-contact and non-product contact surfaces in a **dry (low-moisture) ready-to-eat** food manufacturing facility



When low-moisture foods are produced in dry environments, the pathogen of concern is *Salmonella*. This includes many types of cereal products, baked goods, powders like spices and instant beverages, nuts and seeds, and chocolates and confections.

Summary

- There are several types of environmental monitoring programs that differ in their objectives
- The Preventive Controls for Human Foods Rule
 - Verification activity
 - pathogen environmental monitoring programs (PEMP)
 - contamination of ready-to-eat food a hazard needing a preventive control
- Target organisms in PEMP
 - *Listeria monocytogenes* (wet)
 - *Salmonella* (dry)

In summary, there are several types of environmental monitoring programs and the structure and outcomes or objectives of each will differ.

The Preventive Controls for Human Foods Rule requires that Pathogen Environmental Monitoring programs be established as a verification activity when the hazard analysis determines that contamination of ready-to-eat foods with an environmental pathogen is a hazard that needs a preventive control.

Listeria monocytogenes and *Salmonella* are target pathogens for PEM programs in wet and dry facilities.



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