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Understanding BRCGS Food Safety Production Risk Zones: A Practical Guide for Manufacturers

Introduction

Production risk zoning is often a confusing thicket of thorns for those working in a BRCGS-certified production facility or preparing for certification. BRCGS requires a food manufacturer to define areas of their site based on risk to ensure appropriate preventive controls are in place to maintain a safe food supply. While this is a noble goal and laudable in design, many organizations struggle to understand how these risk zones should be determined and applied to their facilities and processes.

Considering the importance of accurately assessing risk to ensure food safety, Issue 9 of the Food Safety standard now makes it mandatory to utilize Appendix 2 to identify the correct risk zones. This is now an auditable requirement defined in Part II, Clause 4.3.1 of the standard. In addition, clause 4.3.2 requires sites to develop a detailed site map identifying the various risk zones and apply the required risk-mitigation strategies to ensure food safety. The use of the word “shall” in both clauses makes compliance mandatory and non-negotiable.

Historically, risk zones were determined using a flowchart of questions and answers, which was intended to guide users to the correct classification. However, many found this method of determination confusing and inconsistent. With Appendix 2 in Issue 9 of the Food Safety standard providing a clear format, some confusion still remains. In this article, we will simplify the determination process and make it easier to apply.

Understanding the three primary fundamental production zones:

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- 1.) **Open Product Areas** – Any area within the facility where food or ingredients are exposed and not fully enclosed in protective packaging. Examples include blending rooms, production rooms, filling rooms, and packaging rooms.
- 2.) **Enclosed Product Areas** – Areas where ingredients or finished products are fully enclosed in protective packaging. Examples include warehouses and storerooms.
NOTE: Secondary packaging used to move product internally does not qualify as protective packaging if the ingredient will be later exposed (e.g., transferring sugar from a silo to totes for blending).
- 3.) **Non-Production Areas** – Breakrooms, offices, locker rooms, and other areas where no product exposure occurs.

It is safe to assume that the greatest risk to food safety occurs in open product areas, where food is exposed to environmental influences. Therefore, this zone is further divided into High Risk, High Care, Ambient High Care, and Low Risk.



High Risk (Chilled and Frozen)

As part of the HACCP risk assessment, three primary hazard categories—biological, chemical, and physical—shall be controlled in the high-risk zones. The likelihood of pathogenic survival and growth is the primary concern in these areas and must be controlled and minimized. Foods that fall into this zone must therefore:

- 1.) Require freezing or chilling during storage.
- 2.) Have all components fully heat-treated to a minimum temperature of 70°C for two minutes prior to entering the high-risk area.
- 3.) Be susceptible to pathogen growth (or re-growth) during storage or use of the product.
- 4.) Be ready-to-eat, ready-to-heat, or likely to be consumed without adequate cooking.

Foods that may be categorized as high risk (chilled and frozen) include, but are not limited to, cooked sliced meats, fully cooked prepared meals, and cooked crustaceans. Crustaceans are always considered high risk due to consumption patterns and the visual ambiguity between raw and cooked states.



High Care (Chilled and Frozen)

High-care products meet most of the criteria listed above, with one key difference: they are subject to pathogen reduction rather than a full kill step.

For high care, the product must only receive a treatment that reduces the microbial load but does not achieve a full “kill step”. As a result, pathogens may still be present in the finished product and must therefore be controlled through temperature management and shelf-life limitations. It may seem counterintuitive to leave pathogens on a finished product, but the nature of the products classified as high care is such that complete elimination of pathogens is not always possible. For example, fresh produce treated with a chlorine rinse significantly reduces the pathogen load but it will not eliminate them entirely. Maintaining fresh produce at refrigerated temperatures post-rinse will help control the growth and proliferation of any remaining pathogens.



High Care (Chilled and Frozen) cont.

Additional requirements applicable to both high risk and high care include:

- 1.) Complete physical segregation from the low-risk areas (best practice to use solid walls).
- 2.) Strict controls of traffic flow from low-risk to high-risk or high-care areas, including personnel, equipment, utensils, and raw materials.
- 3.) Protection from water and airborne contamination originating from lower-risk areas.

Key distinction:

High Risk: Full pathogen kill step.

High Care: Pathogen reduction step only.

Special Note:

If validated consumer cooking instructions ensure a full kill step, the product may be classified as low risk (Part II, Clause 5.2.4).



Ambient High Care

Ambient high-care products support pathogen survival but not growth. Products that are categorized as ambient high care must meet all of the following requirements:

- 1.) Raw material is prone to contamination with vegetative pathogens (i.e., Salmonella).
- 2.) The process includes a pathogen-reduction or kill step.
- 3.) Finished products are not deliberately temperature-controlled (i.e., ambient storage).
- 4.) Finished products are ready-to-heat, ready-to-eat, or likely to be consumed without adequate cooking.
- 5.) Pathogens could survive in typical conditions of use.

Examples of products classified as ambient high care include chocolate made from raw cocoa beans, milk powder made from raw liquid milk, and peanut butter made from raw peanuts. The term “raw” is emphasized because the pathogen risk may be controlled at the supplier level. Peanut butter made with peanuts that have received a heat treatment at the supplier level would be classified as low risk as the microbiological hazard has been controlled prior to the actual process being completed at the site. However, the site must have documentation in place validating the supplier’s controls to confirm that the pathogen risk has been sufficiently eliminated. If there is not sufficient evidence that pathogenic risk has been controlled at the supplier, the site must enact controls based on a risk assessment, that may be like those requirements set forth in the high-risk or high-care (chilled and frozen) classification.

Low Risk

It is important to note that low risk does not necessarily mean no risk. There is always a risk in food safety in any process step and area, and they must be properly identified and controlled. Low-risk products do not support the survival or growth of pathogens, or will undergo a later “kill step” to eliminate pathogens of concern.

Referring to the HACCP model of risk determination, the focus in low-risk areas is on physical (foreign material) and chemical contamination (allergens).

Products classified as low risk typically include those that require full cooking by the consumer, but classification depends on the actual facility environment and processing steps involved.



Other Considerations In Risk Zone Classifications

Now that we have concluded our clarification of production risk zones, it is important to consider a few additional factors when classifying them.

Enclosed Product Areas:

These may appear within processing areas, not just in warehouses. Examples include:

- Pasteurization systems
- Aseptic filling lines
- Blending tanks
- Enclosed transfer piping

Accurately identifying enclosed zones is essential when creating a site map for Clause 4.3.2.

Non-Product Areas:

As discussed earlier, there is no such thing as no risk in food manufacturing. A risk assessment is always required. Key considerations include:

- 1.) Traffic flow/patterns of production staff, office personnel, transport drivers, visitors, and contractors.
- 2.) Movement of raw materials and finished products both upon receipt and at dispatch.
- 3.) Transition points between areas with zones of different risk levels.
- 4.) Occasional entry into production areas by non-production personnel (i.e., purchasing team members).

Risk mitigation strategies must demonstrate how identified risks are controlled or eliminated.

Conclusion

While production risk zone determination can be complex, the process becomes manageable when you:

- 1.) Fully understand the product and process flow
- 2.) Conduct a thorough risk assessment
- 3.) Apply the correct criteria for each zone
- 4.) Accurately map out all areas within your facility

Accurate and thorough risk zone classification not only supports compliance but also strengthens your food safety program and builds confidence among both your team and your customers.





About EAGLE Certification Group

Since 1994, EAGLE has built a reputation on providing third party auditing services that are objective and value-added. Based in Dayton Ohio, our competent, industry-experienced auditors are well-versed in helping clients ensure their quality, environmental, health and safety, or food safety management systems are robust and effective. EAGLE is ANAB-accredited the North American member of IQNET, a leading international association of certification bodies and fully committed to the global IAF Cert Search database, resulting in transparency and confidence that clients can trust.

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