10 March 2025

Shelf Life Determination of Foods for Special Medical Purposes (FSMP)

Position Paper – Microbiological Tests

Summary

- Monitoring factors typically considered for food safety, including testing for pathogens, microbial burden, or assessment of sterility, are not required when determining FSMP shelf life.
- For powder products, ensuring that a_w straight after manufacturing is less than 0.6 is sufficient and renders any other microbiological tests unnecessary.
- For liquid products, control of microbiological load straight after manufacturing is sufficient and monitoring pathogen content and changes during shelf-life studies is not required.

Safety is a prerequisite for food and must be secured by the manufacturer. In the case of FSMPs that are medical foods for the dietary management of critically ill patients, product safety is especially important.

To ensure food safety, manufacturers regularly perform rigorous ingredient qualifications, implement routine ingredient quality monitoring programs and adopt good manufacturing practices (GMP).

In addition, ingredients used in the manufacture of FSMPs must conform to local legislation and international standards to ensure products placed on the market are both compliant and safe.

During the manufacture of liquid products, processes such as pasteurisation and Ultra-High Temperature (UHT) treatment kill pathogens that may be present and ensure that the product, when packaged, has been adequately heat treated. Once the product is packed and considered commercially sterile or pasteurised and sealed, food safety is ensured by the primary barrier provided by the packaging to eliminate the introduction of spores, yeasts or pathogens. For liquid products, control of microbiological load straight after manufacturing is sufficient and monitoring pathogen content and changes during shelf-life studies is not required.

Powder FSMPs contain very low moisture content within the formulation, making the environment fundamentally much harsher for pathogen growth than in liquid products. The key microbiological control parameter for powder products is to measure Water Activity (a_w), which is a measure of the free and available water vapour that can support microbial growth. Most organisms require a minimum of 0.6 a_w to grow. For powder products, ensuring that a_w straight after manufacturing is less than 0.614 is sufficient and renders any other microbiological tests unnecessary.

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Conclusion

- Monitoring factors typically considered for food safety, including testing for pathogens, microbial burden or assessment of sterility, is not required when determining FSMP shelf life.
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