Inspections, Compliance, Enforcement, and Criminal Investigations

Microbiological Contamination of Equipment Gaskets with Product Contact

[Previous Chapter[1]] [Table of Contents[2]] [Next Chapter[3]]

DEPT. OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION *ORA/ORO/DEIO/IB*

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ITG SUBJECT: MICROBIOLOGICAL CONTAMINATION OF EQUIPMENT GASKETS WITH PRODUCT CONTACT

Background/Discussion

A firm was inspected as part of a district dairy initiative. Original samples of finished product filled by a dedicated filling line revealed that the product was contaminated with pathogenic E. Coli. A follow-up inspection focusing on that particular filling line revealed the presence of that same bacteria in an equipment joint. As a result of that inspection, the firm conducted an extensive clean-up operation and initiated an equipment clean-up procedure that would, under ordinar conditions, appear adequate. However, subsequent testing by a private laboratory revealed that the equipment was still contaminated by this organism, even after extensive equipment cleaning. Further investigation by the firm, equipment manufacturer, and the consulting laboratory, identified the equipment's gaskets as the source of the contamination. Whe the gaskets were replaced, the organism could no longer be detected.

The importance of proper gasket inspection and replacement, as well as sanitization, was a critical factor in this firm's product quality. The use of worn or cracked gaskets may pose a more significant potential contamination source than would appear on the surface.

A deterioration in the gasket also may not be evident without close examination. The presence of minor cracks in the gasket surface would allow the invasion of bacteria. As a gasket continues to deteriorate, these cracks enlarge and become more of a problem. Gaskets are often under pressure when in use which could widen these cracks allowing finished product to come in contact with organisms in the gasket cracks.

Although these gaskets are removed and sanitized when they are no longer under pressure, the cracks may narrow and reduce the exposure potential of sanitizing fluids.

Although not a conclusively proven fact, the information developed during these inspections would indicate equipment gaskets for product contact surfaces to be a potential source of significant problems and particular attention should be paid them during bacteriological inspections.

Tips to Investigators

Investigators conducting inspections of equipment used to process bacteriologically susceptible products (foods, drugs, invitro diagnostic reagents and cosmetics) should pay particular attention to the gaskets in the equipment. Questions to ask should include:

1. Does a physical examination show any evidence of cracking, pitting, or etching of the surface? Such areas will not be sanitizable.
2. How often does the firm inspect and/or replace gaskets? The firm's written procedure should take into account the physical stresses placed on the gasket material as well as any periodic chemical stress which may cause etching of the surfaces.
3. How often does the firm dismantle, clean and sanitize the gaskets? The CIP cleanability of a gasketed joint is

dubious at best. If the gasket was installed even slightly off center, a resulting pocket on the side of the gasket will probably not be subjected to any CIP solutions used.

4. How are the gaskets handled when they are installed initially or after periodic inspection/cleaning? Properly cleaning and sanitizing a gasket is useless if the individual reassembling the equipment re-contaminates the gasket during the process. CIP sanitizing after recontaminating a previously sanitized gasket is useless since, as stated in item 3 above, even slightly off center gaskets cannot be adequately CIP cleaned.
5. Is the gasket material approved for use and does it meet specifications.

Conclusion

If the investigator has reason to believe that the firm is not properly handling their gaskets, finished product samples are warranted. Because of the dilution factor involving production lines used to manufacturer large quantities of liquid or semi liquid products, the investigator should consider sampling the gasket itself. This can best be done by swabbing the gaskets (product contact surfaces only). Aseptic technique is necessary. Immersion of the gasket in a transfer solution o in media itself would not be acceptable since the outer edge of the gasket was probably not a product contact surface. Collection of the gasket in a dry state would be better than nothing, but the firm can always argue that any positive result was from bacteria on non-product contact surfaces (outer edge of the gasket). Collecting the gasket may not be possible if the firm has no replacement. In addition, if a collected gasket is positive, we are also faced with the fact that we may have removed the source of contamination. Consequently any regulatory action, other than that against the product manufactured with the contaminated gasket, may be jeopardized.

[Previous Chapter[4]] [Table of Contents[5]] [Next Chapter[6]]

Page Last Updated: 04/30/2009
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Links on this page:

1. http://wcms.fda.gov/FDAgov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/UCM079650.htm
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