BIOTERRORISM PREPAREDNESS

The Eagle Protect Approach to Safeguarding the Food Supply - Barry Michaels

48 million people get sick, 128,000 people are hospitalised, and 3,000 people die each year from foodborne diseases in the US alone.

The recently introduced Food Safety Modernisation Act (FSMA) aims to ensure the US food supply is safe by shifting the focus from responding to contamination to preventing it. Because disposable gloves are labelled as intermittent contact items, the risk of contamination from these products is not seen as great enough to be included in FSMA requirements. However, gloves are your last line of defence and should be fully included in this new Act.

Currently the international food industry is estimated to use over 22 billion pairs of disposable gloves per year. Most are manufactured in factories in Malaysia, Thailand and throughout Asia where labour conditions can be poor and bioterrorism risks extensive.

Food contact gloves are certified under FDA Title 21 Part 177 which states that the components of the glove comply with the FDA regulations and the gloves consist of, “Substances generally recognised as safe for use in food or food packaging.”

The quality and safety of disposable gloves is limited to Letters of Compliance and Guarantee on the general make and model of the glove, not necessarily the glove you are holding in your hand. There are few controls on the consistency of raw materials, manufacture process and factory compliance on a case by case basis. Opportunity exists for deliberate or accidental contamination within the process, of which the Preventive Controls Qualified Individual (PCQI) may not be aware.

RISKS DURING GLOVE MANUFACTURING

While poor manufacturing practices have resulted in reported instances of physical, chemical and microbiological contamination, the capacity for bioterrorism involving gloves has not been recognised. A great deal of faith is placed in suppliers’ ability to deliver disposable gloves sight unseen. With an end user’s focus often on price, the “ingredients” of a glove’s raw material can be unknowingly changed, lacking qualification or testing and produced under unsanitary conditions.

Commonly used glove elastomers can support a wide assortment of microbial species identified as capable of food bioterrorism. It has been clearly demonstrated in experiments that bacteria persist on gloves and transfer to contact surfaces.

The most comprehensive feature in the new food safety regulations under FSMA is the requirement for a detailed hazard analysis of every step in the manufacturing process of human and animal food.

It is for this reason that performing hazard analysis of the glove manufacturing process and chain of supply is essential. Studies have revealed critical control points important in normal glove production and highly significant in preventing intentional contamination.

RISKS OF BIOTERRORISM CONNECTED TO FOOD AND GLOVE SUPPLY

“I think an epidemic, either naturally caused or intentionally caused, is the most likely thing to cause, say, 10 million excess deaths.” - Bill Gates

Non-governmental organisations (NGO) and public health organisations like the Bill and Melinda Gates Foundation warn that a new form of terrorism could be coming and could be potentially devastating to the civilised world.

Disposable glove safety, efficacy and food security as related to the supply chain is a particularly complex matter. Without transparency in the supply chain of gloves, the

insertion of a bioterrorism agent is a possibility. While glove punctures, rips and tears are unfortunately tolerated during food handling, with only the occasional loss of life, illness or complaint, glove integrity takes on greater importance in the context of bioterrorism.

ACCIDENTAL OR INTENTIONAL GLOVE MANUFACTURING RISKS

Areas of weakness in the food chain include processes that already have risk of accidental contamination - food packaging and glove manufacturing. Weaknesses within either packaging or the glove production process can be exploited and weaponisation is clearly possible.

Expendable individuals may knowingly or innocently spread contamination during glove manufacturing work duties. High turnover, low wages, poor working conditions and difficulty in imposing security in glove manufacturing factories can leave food products at risk. The same is true of food packaging, the difference being that per head count each glove worker is responsible for producing over 2.5 million gloves each year.

Just like food packaging, leak prevention is critical for gloves - a sweaty, punctured and leaking glove is an ideal mechanism for distributing chemical or biological contamination to foodstuffs. Scenarios to combat physical, chemical and microbiological contamination are normal in food safety programs, but potentially deliberate hazards are new factors not normally considered.

HOW TO REDUCE THE RISKS OF GLOVE CONTAMINATION

To effectively combat food contamination, risk managers are putting preventive control systems in place.

It is important to reduce the potential for all adverse events related to normal glove use from chance contamination to the extremes discussed here. This can only be achieved by using Food Safe qualified gloves with significantly higher margins of safety and ethical sourcing - including factory audits, quality control and testing of raw materials. Consistency and attention to detail by a glove supplier is essential for food safety gloves where quality and performance must come without unwanted chemical or microbiological issues.

Numerous studies have shown vinyl gloves have an increased permeability to bacteria and virus, increasing the risk of cross contamination for both the glove users and the food they are handling. To reduce costs, suppliers often allow inexpensive phthalates and BPA to be added during manufacturing – reasons why vinyl gloves are banned in Japan for food handling. Adverse health effects of exposure to BPA and phthalates in US food and occupational settings is estimated to result in US$175 Billion in healthcare costs.

Because of their chemical resistant properties, high strength and thin wall construction, nitrile gloves can be used as an adjunct to personal protection equipment where applicable to prevent exposure.

NEXT GENERATION SAFETY ASSURANCE CERTIFICATION

Most cosmetic and drug manufacturers check every lot of raw materials against an internally developed standard.

This level of chemical and microbiological safety assurance can be achieved with disposable gloves by select and proprietary chemical analysis of proven effectiveness. Eagle Protect will progressively rely on “Fingerprinting” gloves to assure raw material composition and “sanitary integrity”. This ensures against the risk of contamination or change in raw materials during manufacturing, providing manufacturers and food service customers consistent food-safe gloves with an improved accidental or intentional contamination profile.

There are identified potential risks associated with disposable gloves and food chain contamination. To improve shelf-life and reduction in the risks of foodborne illnesses, glove distributors should provide documented supply chain transparency and manufacturing hazard mitigation. This should include all issues related to glove factory operation, hygienic and ethical labour practices, demonstrated through a multi-levelled certification process.

The disposable glove industry and food producers reliant on critical glove supplies have been able to run for a long period without any accountability to the food chain. Fortunately, times have changed and a greater level of safety assurance is mandated by the government, the food industry and customers.

Full details and references for all the information included in this paper can be found in the full white paper Bioterrorism Preparedness, ***The Eagle Protect Approach to Safeguarding the Food Supply****, written by Barry Michaels. Contact us at info@eagleprotect.co.nz for copies of the White Paper.*

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